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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

{SWD(2025) 1050-1052 final}

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The medical devices sector is a very diverse and innovative driver of economic growth in Europe. The sector plays a key role in boosting the competitiveness of the European Union and ensuring the functioning of the Member States' healthcare systems and, ultimately, achieving a high level of public health protection. A medical device can be any instrument, apparatus, appliance, software, implant, reagent for *in vitro* use, or any material or article intended by the manufacturer to be used, alone or in combination with other materials or articles, for human beings for a medical purpose, e.g. for the diagnosis, treatment, alleviation, prevention, monitoring, prediction or prognosis of a disease, injury or other condition.

Medical devices cover a wide range of products, such as sticking plasters, syringes, surgical masks, eyeglasses, wheelchairs, medical apps, body scanners, and implantable devices such as heart valves, pacemakers or knee and hip replacement joints. Examples for *in vitro* diagnostic medical devices (IVDs) include influenza or COVID-19 tests, HIV tests, gene mutation tests or blood grouping tests. According to the World Health Organization, there are an estimated 2 000 000 different kinds of medical devices on the global market, categorised as belonging to more than 7 000 generic device groups[1]. There are more than 38 000 medical technology companies in Europe. Small and medium-sized enterprises (SMEs) make up around 90% of the industry, most of which are small and micro-sized companies which employ fewer than 50 people. Altogether, the medical technology industry employs more than 930 000 people in Europe. The European medical technology market was estimated to be worth approximately EUR 170 billion in 2024[2].

Regulation (EU) 2017/745 on medical devices (the 'Medical Devices Regulation' or 'MDR')[3] and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (the '*In Vitro* Diagnostic Medical Devices Regulation' or 'IVDR')[4] of the European Parliament and of the Council (collectively referred to in this proposal as 'the Regulations') provide a strengthened regulatory framework for medical devices and *in vitro* diagnostic medical devices ('IVDs'). As set out in their first two recitals, the MDR and IVDR aim to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices and for *in vitro* diagnostic medical devices, which ensures a high level of safety and health while supporting

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1 https://www.who.int/health-topics/medical-devices#tab=tab_1 (accessed 17.10.2025).

2 https://www.medtecheurope.org/resource-library/medtech-europes-facts-figures-2025/ (accessed 17.10.2025). The data is for EU27, Iceland, Norway, Switzerland and UK.

3 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

4 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

innovation. These Regulations aim to ensure the smooth functioning of the internal market, taking as a base a high level of protection of health for patients and users, and taking into account the SMEs that are active in this sector.

To achieve these objectives and to address issues with the previously applicable legislation, the Regulations have, among other things, set stricter requirements for the level of clinical evidence that must be gathered by manufacturers to demonstrate compliance of their devices with the relevant rules. The Regulations also provide for a more robust system of conformity assessment to check the quality, safety and performance of devices placed on the EU market. Under the MDR and the IVDR, devices are divided into four risk classes[5], depending on their intended purpose and inherent risks. Depending on the risk class of the device, the manufacturer must involve an independent third-party conformity assessment body ('notified body') in the conformity assessment, before it can affix a CE marking to the device and place it on the market. When the MDR and IVDR took effect, the number of designated notified bodies was very low, which created bottlenecks in the mandatory pre-market certification process. To date, 51 notified bodies have been designated under the MDR and 19 under the IVDR.

The MDR took effect on 26 May 2021[6], and the IVDR on 26 May 2022. The much stricter requirements established by the Regulations, which also apply to existing devices, the limited certification capacity of the notified bodies and the insufficient preparedness of the manufacturers posed the risk of supply shortages and disappearance of critical devices from the market. Therefore, the transitional period specified in Article 120 of the MDR has been extended by Regulation (EU) 2023/607[7] and will end either on 31 December 2027 or on 31 December 2028, depending on the device's risk class and subject to certain conditions. The transitional periods specified in Article 110 of the IVDR have been extended by Regulation (EU) 2022/112[8] and by Regulation (EU) 2024/1860[9]; they will end on either

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5 Medical devices are classified in class I (low risk), class IIa (low to medium risk), class IIb (medium to high risk) and class III (high risk); IVDs are classified in class A (low individual and low public health risk), class B (moderate individual and low public health risk), class C (high individual and moderate public health risk) and class D (high individual and high public health risk).

6 Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (OJ L 130, 24.4.2020, p. 18) had postponed the date of application of Regulation (EU) 2017/745 from 26 May 2020 to 26 May 2021 due to the COVID-19 outbreak and the associated public health crisis.

7 Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices (OJ L 80, 20.3.2023, p. 24).

8 Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and the deferred application of conditions for in-house devices (OJ L 19, 28.1.2022, p. 1).

9 Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain *in vitro* diagnostic medical devices (OJ L 2024/1860, 9.7.2024).

31 December 2027, 31 December 2028 or 31 December 2029, depending on the IVD's risk class and subject to certain conditions, which are similar to those provided for in the MDR.

The repeated extension of the transitional periods was only a short-term solution to mitigate the risk of shortages. It could not solve the underlying structural problems in the implementation of the MDR and IVDR. In view of the many challenges in the implementation of the two Regulations, in 2024 the European Commission launched a targeted evaluation of the MDR and IVDR. Despite the significant progress that has been made in the practical implementation of the MDR and IVDR, the targeted evaluation (which is being finalised at the same time as this proposal) has identified shortcomings in the regulatory framework. These weaknesses affect the availability of devices and the competitiveness of EU manufacturers (in particular of the many micro, small and medium-sized companies) and hinder innovation in medical technology. This, in turn, has a negative impact on healthcare quality and patient safety. The results of the targeted evaluation are presented in Section 3 of this explanatory memorandum.

This proposal aims to streamline and future-proof the regulatory framework. Its main objective is to simplify the applicable rules, reduce the administrative burden on manufacturers and enhance the predictability and cost-efficiency of the certification procedure by notified bodies, while preserving a high level of public health protection and patient safety, and thus to help achieve the initial objectives of the Regulations. The objectives of the MDR and IVDR are still pursued by all relevant actors. However, the lack of sufficiently predictable timelines for the certification process and the diverging practices across the EU continue to undermine the efficiency of the process to obtain the CE marking. Moreover, several requirements under the Regulations are disproportionate to the actual risks posed by the devices, which results in unnecessarily high costs and burdens. Overly onerous requirements may prompt manufacturers, especially SMEs, to discontinue supplying devices or to delay their launch, with potential negative consequences for patient care and public health. They may also negatively impact the competitiveness of the EU medical devices market compared to other jurisdictions around the world.

This proposal is a response to requests from the European Parliament[10], several Member States[11] and numerous stakeholders for a simplification of the regulatory framework for medical devices and for measures to ensure the availability of devices. A new regulation is needed to remedy the problems that have been identified, which otherwise would have a considerable impact on the medical devices market and, consequently, on the quality of healthcare provided to patients in the EU.

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10 European Parliament resolution of 23 October 2024 on the urgent need to revise the Medical Devices Regulation (2024/2849(RSP)) (OJ C, C/2025/485, 29.1.2025 ELI: http://data.europa.eu/eli/C/2025/485/oj).

11 Joint paper of Croatia, Finland, France, Germany, Ireland, Luxembourg, Romania, Malta and Slovenia on necessary reforms in MDR and IVDR: priorities / main points (Council of the European Union, 28.11.2024, 15380/24).

The proposal aims to improve the functioning of the current regulatory framework, in particular as regards the smooth functioning of the single market, while ensuring a high level of health protection for patients. It builds on the key features of the existing framework, notably the decentralised approach (whereby responsibilities are allocated to the Member States) and the involvement of notified bodies in the conformity assessment procedure, like in other EU legislation based on the New Legislative Framework. However, the aim is to establish a leaner and more cost-effective regulatory framework and to promote further harmonisation, creating a more competitive and innovative EU market.

The Medical Device Coordination Group (MDCG) was established in accordance with Article 103 of the MDR and is composed of representatives of the national competent authorities and chaired by the Commission. In the proposal, the MDCG is retained as the main governing body.

The proposal strengthens the coordination between notified bodies through the coordination group (NBCG-Med) which was established in accordance with Article 49 of the MDR and creates a direct reporting line from the NBCG-Med to the MDCG. While notified bodies will remain under the responsibility of the Member States, the proposal aims to improve the oversight and regular monitoring of notified bodies through involvement of experts from the Commission and other Member States.

Expert panels[12] have been introduced by the MDR to provide scientific and clinical advice relating to medical devices and IVDs, as well as to provide opinions on the clinical evaluation assessment reports drawn up by notified bodies for certain high-risk devices and on the performance evaluation reports concerning certain high-risk IVDs. Since 2022, the European Medicines Agency (EMA) has provided the secretariat for the expert panels[13]. The proposal aims to broaden the scope of expertise available in the expert panels and expand their advisory function in regulatory decision-making. In addition, the Commission's proposal also includes support from the EMA to the competent authorities to improve coordination between them, especially with regard to borderline cases and classification issues, derogations from applicable conformity assessment procedures and possibly other requirements, clinical evaluations and investigations, vigilance and market surveillance.

- **Consistency with existing policy provisions in the policy area**

Given the urgent need to take action, the proposal is presented as an immediate follow-up to the targeted evaluation of the MDR and IVDR. It pursues similar objectives as the Commission proposals adopted in April 2023 for a reform of the EU pharmaceuticals legislation[14]. Consistency with the proposed regulations replacing Directive 2001/83/EC and Regulation (EU) No 726/2004 is ensured. This proposal is also consistent with the

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12 European Commission website, *Medical Devices – Expert Panels* - *Overview*

13 Article 30 of Regulation (EU) 2022/123 on a reinforced role of the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

14 Reform of the EU pharmaceutical legislation - Public Health

Commission proposal for a Biotech Act[15], scheduled for adoption at the same time as this proposal, which contains, among other things, proposed amendments to the Clinical Trials Regulation[16], such as a coordinated assessment procedure for combined studies involving medicinal products, IVDs and/or medical devices. This proposal also aligns the relevant MDR provisions with the new Regulation on substances of human origin (SoHO)[17].

- **Consistency with other Union policies**

The proposal contributes to the achievement of the Commission's objective to improve the EU's competitiveness by making business easier and supporting research and innovation. The Competitiveness Compass[18] reiterates the need to simplify the regulatory environment, to reduce burden and to foster innovation, in particular in technology-based sectors.

The Communication entitled 'A simpler and faster Europe'[19] has set new targets for the reduction of administrative burden and for prioritising new simplification measures.

This proposal is also consistent with the Commission's Strategy for European Life Sciences[20], which pointed out that the risks of losing competitiveness to other regions are especially high in areas such as medical devices, as legislation is not sufficiently innovation-friendly, future-proof and lacks clear paths to access markets. The Commission therefore committed to propose a legislative initiative striking the balance between simplifying EU regulations related to medical devices and *in vitro* diagnostics, and effectively protecting patient safety and public health, also considering health emergencies.

The proposal is consistent with EU policies in the fields of safety, health and environment, as it safeguards a high standard of patient safety and public health protection, while reducing overly burdensome requirements and streamlining procedures. The proposal is complementary to EU policies in the fields of single market and artificial intelligence, as it lays down regulatory tools which pursue the same objectives as the existing provisions in those areas.

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15 Proposal for a Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act), COM(2025)1022 of 16 December 2025.

16 Regulation (EU) No 536/2014, ELI: http://data.europa.eu/eli/reg/2014/536/oj.

17 Regulation (EU) 2024/1938, ELI: http://data.europa.eu/eli/reg/2024/1938/oj.

18 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, A Competitiveness Compass for the EU, COM(2025)30 final, 29.1.2025.

19 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A simpler and faster Europe: Communication on implementation and simplification, COM(2025)47 final, 11.2.2025.

20 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, Choose Europe for life sciences, A strategy to position the EU as world's most attractive place for life sciences by 2030, COM(2025)525 final, 2.7.2025.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

As the proposal amends two existing Regulations, the legal basis for the proposal is the same as that in the Regulations to be amended, namely Article 114 and Article 168(4) point (c) of the Treaty on the Functioning of the European Union (TFEU). The measures proposed for this amending regulation have as their objective to preserve and enhance the smooth functioning of the single market as regards medical devices and *in vitro* diagnostic medical devices, while preserving the performance and safety of devices for patients and users.

• Subsidiarity (for non-exclusive competence)

The MDR and IVDR have introduced a common regulatory framework at EU level, as the objectives of these Regulations could not be sufficiently achieved through national intervention. These objectives are, specifically, to ensure a high level of protection of health for patients and users and the smooth functioning of the single market, and to avoid potential market disruption. To address the identified problems, action at EU level is considered less costly and more efficient than national measures in all Member States. For this reason, the proposed amendments to the MDR and IVDR must be made at EU level.

• Proportionality

The proposed amendments do not go beyond what is necessary to achieve the objectives of simplification and burden reduction to ensure that the intended purpose of both Regulations can be attained. That purpose is to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices and for *in vitro* diagnostic medical devices which guarantees a high level of protection of public health and patient safety and the smooth functioning of the single market for such devices.

• Choice of instrument

The Commission proposes a regulation of the European Parliament and of the Council. This is the most suitable legal instrument as only a regulation, with its uniform application, binding nature and direct applicability, can provide the necessary degree of uniformity needed to improve the functioning of the single market as regards medical devices and *in vitro* diagnostic medical devices.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations / fitness checks of existing legislation**

The Commission has just concluded a targeted evaluation of the Regulations[21]. This proposal draws on the findings of the evaluation.

Overall, the evaluation found that the benefits of the Regulations for patients and healthcare systems are materialising by strengthening device safety and performance and increasing transparency. However, these achievements come at high and often disproportionate compliance costs, caused also by high regulatory complexity.

The evaluation found that the Regulations have strengthened the regulatory framework through stricter requirements on the designation and oversight of notified bodies, the conduct of conformity assessments, and the generation of clinical evidence. However, the three dimensions are closely interlinked, and weaknesses in one area affect the entire system. A fragmented and lengthy designation process reduces available capacity and creates inconsistencies in oversight, which in turn contributes to divergent conformity assessment practices. At the same time, incomplete or unevenly assessed clinical evidence prolongs assessments and undermines predictability, while limiting the ability to demonstrate that the Regulations' safety objectives are met. Although progress is evident, the combined effect of capacity constraints, fragmented oversight and uneven evidence requirements means that efficiency, harmonisation and effectiveness remain below expectations. This has led to a perceived unpredictability and disproportionality of the regulatory framwork, undermining trust of stakeholders in the system. More precisely, the evaluation shows that this results in a decrease in the availability of certain devices (e.g. innovative and niche devices), which has a negative impact on the protection of patients and industrial competitiveness.

The evaluation highlights several shortcomings and inefficiencies in the current regulatory framework, particularly regarding simplification and streamlined procedures. A fragmented and disharmonised regulatory framework has resulted in several inefficiencies and unnecessary burdens for stakeholders, who call for a more centralised governance structure. An unanticipated increased administrative burden appears to originate from redundant reporting and unnecessary duplication of work, posing significant challenges for stakeholders. The unpredictability and disproportionality of the system further compound these concerns, particularly for economic operators seeking clarity and consistency in requirements that would make it possible to foster innovation without compromising safety. In addition, digital solutions are often cited as potential avenues to alleviate some of these burdens, enhance efficiency and reduce resource constrains. The fragmentation of governance structures,

[21] Commission Staff Working Document on the Targeted evaluation of Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on *In Vitro* Diagnostic Medical Devices, SWD(2025)1051.

overlapping reporting requirements and limited digitalisation identified contribute to increased administrative and adjustment costs for both authorities and economic operators.

In summary, the targeted evaluation shows that:

- certain requirements, especially in relation to conformity assessment procedures, are overly complex, burdensome, lengthy and costly;
- the application of legal requirements by national authorities and notified bodies is not sufficiently aligned;
- current coordination mechanisms are not sufficiently efficient and effective;
- there is no sufficient technical-regulatory advice available at EU level;
- adaptive pathways for breakthrough innovation and orphan or 'niche' devices do not exist;
- the Regulations have unintended negative impacts on innovation, competitiveness and patient care;
- there is a need for improved coherence with other EU law, such as the Clinical Trials Regulation.

The evaluation has demonstrated that there is a potential to simplify and to reduce burden relating to the implementation of both Regulations, without undermining their main objectives.

- **Stakeholder consultations**

In addition to the continuous consultations with Member States and stakeholders taking place as part of the Medical Devices Coordination Group, and the public and targeted consultation activities informing the targeted evaluation, the Commission launched a call for evidence on the targeted revision of the MDR and IVDR.

It was possible to submit feedback from 8 September to 6 October 2025[22]. A total of 427 individual submissions[23] and 166 attachments[24] were considered valid (the final analysis was based on 165 of these attachments)[25].

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22 European Commission, *Medical devices and in vitro diagnostics – targeted revision of EU rules*, Have Your Say webpage.

23 The figures include one contribution discarded as not respecting the feedback rules; five contributions from four contributors were removed as considered duplicates, and 14 contributions were merged into six contributions as considered complementary feedback.

24 As part of the 171 attachments received in the call for evidence, five were not taken into account in the analysis (one attachment from the discarded feedback, two attachments were part of the above duplicates and one document was sent three times by one contributor).

25 One attachment sent three times by one contributor was considered off-topic.

In terms of stakeholder groups, companies and businesses were the largest contributors (199 contributions, 46.6%) followed by business associations (61 contributions, 14.29%). The other respondents were non-governmental organisations (36 contributions, 8.43%), academic and research institutions (31 contributions, 7.26%), public authorities (13 contributions, 3.04%) and trade unions (6 contributions, 1.41%). Feedback was also provided by notified bodies (5 contributions, 1.17%) and consumer organisations (1 contribution), as well as by individuals (37 submissions from EU citizens (8.67%) and 8 from non-EU citizens (1.87%)). Some stakeholders selected the option 'Others' (30 contributions, 7.03%). A large majority of contributing companies/businesses represented SMEs (129 contributions , 64.8%) including 34 medium-sized, 54 small and 41 micro-sized companies.

In terms of geographical scope, the respondents were mostly from Germany (100 submissions, 23.42%), Belgium (48 submissions, 11.24%) and France (39 submissions, 9.13%).

Feedback to the call for evidence indicated that respondents agreed with the identified hurdles stemming from the Regulations. They referred to their disproportionate costs, high administrative burden and overall regulatory complexity, also echoing the findings of the targeted evaluation. Stakeholders showed overall broad support for measures aiming at simplifying and making the regulatory framework more proportionate and efficient, reducing administrative burden, and allowing for more flexibility to support innovative devices to reach the market.

Respondents across all stakeholder groups overall recognized the objectives of the Regulations and stressed that maintaining safety standards and a high level of public health, including by ensuring the availability of devices or by supporting innovation for small population groups, should remain at the centre of the revision.

Overall, stakeholders underlined the need for a risk-based approach to requirements, supported greater digitalisation and a more efficient governance. Feedback included proposed changes related to several areas, including clinical and post-market data requirements, simplification and greater predictability of the conformity assessment process, as well as changes related to audits and post-market surveillance

Feedback also particularly emphasized the implications of the Regulations for SMEs as costs to comply with the requirements are viewed as particularly disproportionate for SMEs; many stakeholders are asking for SMEs' needs to be taken into account.

Some stakeholders were also in favour of greater use of digital tools. There were also requests for simplified and enhanced governance, including to improve the predictability and ensure a harmonised interpretation of the regulatory system.

Finally, stakeholders supported measures enhancing the consistency with other EU legislative frameworks, such as, EU legislation on clinical trials and artificial intelligence.

The Commission also launched a series of targeted surveys, including one survey dedicated to small and medium-sized manufacturers of medical devices, and organised several workshops.

- **Collection and use of expertise**

The proposal is based on the findings of the targeted evaluation and the stakeholder consultations described above.

- **Impact assessment**

The proposal addresses the issues identified during the targeted evaluation. The proposed revision of the MDR and IVDR consists of targeted simplification measures (for which there are no viable alternatives), that seek to reduce burden and ensure greater predictability of the legislative framework. The proposed amendments do not intend to modify the objectives of the legislation, thus ensuring the continued availability of safe and innovative devices and safeguarding a high level of patient safety, public health and healthcare. In this context, an impact assessment was not deemed necessary nor appropriate, in terms of timing and efficiency.

Instead, the proposal is accompanied by a Commission staff working document which explains the proposed measures and presents the evidence and its analysis, as well as stakeholders' views. That Commission staff working document contains a cost-savings estimate[26]. Overall, the combined quantifiable impact of the simplification measures described in that document, taking into account the limitations and assumptions outlined throughout, is estimated to reach more than €3 billion per year. Alongside financial relief, the measures aim to put in place a proportionate, efficient and flexible framework, increase legal certainty, support more coherent implementation across the Union and sustain the high level of health protection set out in the MDR and IVDR. By supporting a more efficient and innovation-friendly system, the proposed measures ultimately help ensure that patients continue to have access to the devices they need.

- **Regulatory fitness and simplification**

The proposal contributes to the Commission's commitment to simplify EU legislation and to reduce regulatory burden for people, businesses and administrations in the EU, improving its competitiveness and resilience.

The proposal to streamline procedures and to reduce the burden on manufacturers, distributors and notified bodies is expected to decrease compliance costs for SMEs, large companies and other stakeholders in the relevant sectors. The simplification of administrative procedures will significantly reduce uncertainty, ensuring greater predictability for companies, allowing them to plan their research and development activities more efficiently. The more streamlined processes for certification and for oversight of notified bodies will boost the competitiveness of the relevant EU sectors, particularly for SMEs, which will be able to respond more quickly to the changing market conditions and customer needs. More efficient and predictable processes will make the EU companies concerned more attractive to both domestic and foreign investors which could lead to increased investment and growth in the sector.

[26] Commission Staff Working Document on Cost-savings, SWD(2025)1050.

- **Fundamental rights**

The proposal respects the fundamental rights and principles laid down in the Charter of Fundamental Rights of the European Union[27]. In particular, it maintains the right of each person to respect for their physical and mental integrity (Article 3), the protection of personal data (Article 8) and the freedom to conduct a business (Article 16) and the right to property (Article17). Moreover, the proposed simplification measures, the expected reduction in administrative burden and the measures to support patient-centred innovation and the availability of devices, including those for small patient populations, support the right of access to preventive care and the right to benefit from medical treatments. They also ensure a high level of human health protection, as laid down in Article 35 of the Charter.

4. BUDGETARY IMPLICATIONS

The proposal has budgetary implications for the EU, primarily with regard to additional resources needed to ensure: (1) a stronger oversight of notified bodies and a uniform application of the regulatory framework; (2) access to external additional scientific, technical and regulatory expertise to support evidence-based decision-making; and (3) support from the European Medicines Agency (EMA) for better coordination of activities undertaken by national authorities in relation to the implementation of the MDR and IVDR, in particular in the areas of vigilance and market surveillance, borderline and classification decisions, clinical investigations and performance studies, and derogations in exceptional cases relating to patient health and safety. The 'financial statement' provides detailed information about the budgetary implications and the human and administrative resources required. This approach leverages the established role of expert panels and the EMA to efficiently address the needs of the sector within the current system framework, thereby drawing on the strengths of existing EU regulations.

The proposal authorises the Commission to set fees for certain activities required under the existing MDR and IVDR and the proposed amendments, such as the assessment and monitoring of notified bodies and the provision of scientific and regulatory advice. Those activities may therefore be funded, at least partially, through fees, with the possibility to introduce reduced rates for SMEs. However, other activities, especially those relating to improved coordination among national authorities to improve the functioning of the single market and simplify compliance for economic operators, cannot at this stage be financed from the financial contributions of the entities subject to the regulatory framework. A specific rule for user fees is needed, as such rules exist in other sectors in the EU and other jurisdictions.

The impact on the EU budget of the costs of enhanced coordination will eventually reduce costs for economic operators thanks to benefits stemming from uniform practices in the singlemarket, streamlined procedures and a more robust and predictable regulatory infrastructure that enhances competitiveness and stimulates innovation. Moreover, the

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27 EUR-Lex - 12012P/TXT - EN - EUR-Lex

proposed amendment strengthens the EU's ability to effectively prevent and respond to public health threats, such as shortages in the supply of medical devices and safety concerns, thereby minimising the costs associated with any inefficiencies in the regulatory framework. Crucially, this effort also aims to simplify existing regulations, reduce administrative burdens, and refine the certification processes for notified bodies, leading to a significant reduction in overall expenses for manufacturers, all while safeguarding public health and patient safety.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The impact of the proposal will be monitored through existing reporting and oversight mechanisms, as part of the regular follow-up measures set out in the Regulations. In addition, the Commission proposes to carry out another evaluation of the application of the MDR and IVDR five years after the proposed amendments enter into effect.

- **Detailed explanation of the specific provisions of the proposal**

The proposal is structured as follows:

Article 1: Amendments to Regulation (EU) 2017/745

Article 2: Amendments to Regulation (EU) 2017/746

Article 3: Amendments to Regulation (EU) 2022/123

Article 4: Amendments to Regulation (EU) 2024/1689

Article 5: Entry into force

The amendments can be summarised as follows, by main topic, Articles concerned and specific provisions of the proposal:

Amendments to Regulation (EU) 2017/745 on medical devices (MDR) and to Regulation (EU) 2017/746 (IVDR)	
TOPIC 1: SIMPLIFICATION AND PROPORTIONALITY	
Articles	Specific provisions of the proposal
Person responsible for regulatory compliance (PRRC) (MDR: Article 15, IVDR: Article 15)	Removal of the detailed qualification requirements for the PRRC and removal of the obligation that SMEs, which rely on an external PRRC, need to have the PRRC 'permanently and continously' available, but only available.
Validity of certificates and recertification (MDR: Article 56, IVDR: Article 51)	The maximum period of validity of certificates (currently 5 years) is removed. Instead of recertifying devices, notified bodies will carry out periodic reviews proportionate to the risk of the device while

	the certificate is valid.
Clinical evidence, non-clinical data and clinical data (MDR: Article 2, point 48, Article 61, Annex II, Annex XIV , IVDR: Annex XIII)	A wider range of data may qualify as clinical data. The conditions for relying on clinical data of an equivalent device are made more flexible. In Article 61 MDR, the possibility to demonstrate a device's safety and performance based on non-clinical data alone is expanded. The use of 'New Approach Methodologies', such as in silico testing, is promoted.
Well-established technologies (MDR: Article 2, point 72, Article 18, Article 32, Article 52, Article 61, Article 86)	A definition of 'well-established technology device' is introduced for devices which will be subject to more proportionate requirements, replacing the lists of devices in the current Articles 18(3), 52(4) and 61(6)(b) MDR.
Repackaging and relabelling (MDR : Article 16, IVDR: Article 16)	The requirements for a notified body certificate for relabelling and repackaging activities, as well as the prior notice obligation, are removed.
Classification rules (MDR: Annex VIII)	Some classification rules are adapted resulting in lower risk classes for certain devices, such as reusable surgical instruments, accessories to active implantable devices and software.
TOPIC 2: REDUCTION OF ADMINISTRATIVE BURDEN	
Articles	Specific provisions of the proposal
Summary of safety and (clinical) performance (MDR: Article 32, IVDR: Article 29)	The scope of devices for which the manufacturer must provide a summary of safety and (clinical) performance (SS(C)P) is reduced to those devices for which the notified body must conduct a technical documentation assessment. As the draft SS(C)P is part of the documentation to be submitted to the notified body, a separate validation by the notified body is no longer required.
Periodic Safety Update Report (MDR: Article 86, IVDR: Article 81)	The frequency according to which manufacturers are obliged to update periodic safety update reports (PSUR) is reduced. The review of the PSUR by the notified body will be part of its surveillance activities.

Reporting timeline of certain serious incidents in the framework of vigilance (MDR: Article 87, IVDR Article 82)	Manufacturers will have 30 days (instead of 15 days) for reporting serious incidents which are not related to public health threats, death or serious deterioration of health.
Changes after certification (MDR: Annex VII, IVDR: Annex VII)	Notified body must distinguish between changes regarding the quality management system or the approved device that manufacturers can implement without prior notification, without prior approval or only after approval by the notified body. Where appropriate, notified body and manufacturer shall agree on a predetermined change control plan.
Authorisation or notification of certain performance studies (IVDR: Article 58)	Performance studies involving only routine blood draws will not be subject to prior authorisation. The notification of performance studies on companion diagnostics using left-over specimens will be removed.
TOPIC 3: INNOVATION AND AVAILABILITY OF DEVICES FOR SPECIAL PATIENT GROUPS OR SITUATIONS	
Articles	Specific provisions of the proposal
In-house devices (MDR: Article 5(5), IVDR: Article 5(5))	The conditions for the manufacture and use within health institutions are made more flexible, e.g. allowing the transfer of in-house devices if this is in the interest of patient safety or public health). Under the IVDR, the condition that there is no equivalent device on the market is removed. Central laboratories manufacturing and using tests exclusively for clinical trials are added to the scope of the in-house device exemption.
Interruption or discontinuation of supply of certain devices (MDR: Article 10a, IVDR: Article 10a)	A central IT tool for the reporting and information exchange will be provided in Eudamed or interoperable with Eudamed. EMA will develop a methodology to identify devices falling within the scope of the reporting obligation and draw up a list of such devices.
Conformity assessment procedures for breakthrough devices or orphan devices (MDR: new Article 52a, IVDR: new Article	Criteria for breakthrough devices and orphan devices are introduced. After 'designation' by an expert panel, breakthrough devices and orphan devices will be subject to a priority

48a)	and rolling review. Manufacturers have access to expert panels' advice.
Derogations for public health emergencies, disasters or crises (MDR: Article 59, new Article 59a, IVDR: Article 54, new Article 54a)	The Commission may authorise the placing on the market of devices in the event of a public health emergency on its own initiative. Competent authorities may authorise derogations from manufacturing, design or intended purpose of CE-marked devices during serious cross-border health threats, disasters or crises.
Regulatory sandboxes (MDR: new Articles 59b and 59c, IVDR: new Articles 54b and 54c)	Member States and the Commission may establish regulatory sandboxes to address needs of emerging technologies.
Reprocessing of single-use devices (MDR: Article 17)	Manufacturers will be obliged to provide a justification for a 'single-use' claim. All devices that are not intended for single-use can be reprocessed in accordance with the instructions provided by the manufacturer. A person who fully refurbishes a single-use device will be the manufacturer of the fully refurbished device. The provision will become applicable five years after entry into force.
Kits (IVDR: new Article 19a)	Clarification regarding the composition of kits as defined in Article 2(11) IVDR.
'Grandfathering' of legacy orphan devices (MDR: Article 120, IVDR: Article 110)	Orphan devices that were CE marked under the former Directives and for which an expert panel has confirmed that they meet the criteria of 'orphan device' may continue to be placed on the market beyond the transitional periods, subject to conditions.
Nanomaterial (MDR: Annex I, Annex VIII)	The outdated definition of nanomaterial in Article 2 MDR will be deleted and replaced by a reference to the Commission Recommendation of 10 June 2022 on the definition of nanomaterial in the provisions of Annex I and Annex VIII concerning nanomaterial.
TOPIC 4: PREDICTABILITY AND COST-EFFICIENCY OF CERTIFICATION	
Articles	Specific provisions of the proposal
Structured dialogue (MDR: Annex VII,	A legal basis for notified bodies and

IVDR : Annex VII)	manufacturers to conduct, pre- and post-submission, a structured dialogue based on documented procedures will be introduced.
Conformity assessment procedures (MDR: Article 52, Annexes IX, X, XI**,** IVDR: Article 48**,** Annexes IX, X, XI)	The involvement of notified bodies in the conformity assessment of lower and medium risk devices (class IIa and IIb and class B and C) will be reduced (technical documentation assessment of one representative device for a generic device group, for a category or for the entire portfolio). No systematic technical documentation assessment of representative devices will be required during surveillance activities. Class A sterile IVD will not require notified body involvement. Notified bodies will have the possibility to replace on-site audits by remote audits. Where justified due to absence of safety issues, surveillance audits should be conducted only every two years. Unannounced audits should be conducted 'for-cause'. Reduced timelines for consultation of medicinal products and SoHO authorities.
Clinical evaluation consultation procedure (MDR: Article 54), performance evaluation consultation procedure and early advice (IVDR: Article 48, new Article 56a)	The scope of the CECP will be limited to class III implantable devices with the empowerment of the Commission to add other types of devices by delegated act. The PECP will be removed. Instead, the possibility of early advice from expert panels for class C and D IVDs will be introduced.
Notified body fees (MDR: Article 50)	Fee reductions for micro and small manufacturers and for orphan devices. The Commisison will be empowered to set level and structure of notified body fees.
TOPIC 5: COORDINATION WITHIN DECENTRALISED SYSTEM	
Articles	Specific provisions of the proposal
Regulatory status of products and classification of devices (MDR: Article 4, new Article 4a, new Article 51a, new Article 51b, IVDR: Article 3, new Article 3a, new Article 47a, new Article 47b,)	The coordination among competent authorities regarding the qualification of a product and the classification of a device ('Helsinki procedure') will be codified, with the possibility to request opinions from expert panels.

Designation and monitoring of notified bodies (MDR: Article 36-44, IVDR: Article 31 referring to the MDR provisions)	The assessment of applications from conformity assessment bodies and he designation/notification of notified bodies will be streamlined with the involvement of joint assessment teams composed of the national authority responsible for notified bodies, experts nominated by the Commission and experts nominated from other Member States. Joint assessment teams will be involved in the monitoring of notified bodies after they have been designated, at least every two years. The full reassessment of notified bodies every five years will be removed. The Commission will be empowered to set the level and structure of fees and recoverable costs for the designation and monitoring of notified bodies.
Dispute resolution mechanism between manufacturers and notified bodies (MDR: Article 35, IVDR: Article 31 referring to the MDR provisions)	The authority responsible for notified bodies will have an 'ombudsperson' role in case of disputes between manufacturers and notified bodies.
Coordination of notified bodies (MDR: Article 49, Article 31 referring to the MDR provisions)	The obligation of notified bodies to participate in the notified bodies coordination group (NBCG-Med) will be strengthened. NBCG-Med will report to the MDCG.
Enhanced role of external expertise available to the regulatory system (MDR: Article 106, new Article 106a IVDR: Article 100)	The role of expert panels and their composition will be broadened, involving them e.g. in determination of the regulatory status of products and classification of devices. Expert panels should be able to provide scientific, technical, clinical and regulatory advice to the Commission, Member States, the MDCG, notified bodies and in certain cases to manufacturers. The EMA will continue to provide the secretariat for the expert panels. The functions of expert panels and expert laboratories, currently regulated together in Article 106 MDR, will be clarified through a separate provision on expert laboratories.
Support from the EMA for the coordination	The EMA will provide scientific technical

of competent authorities (MDR: new Article 106b)	and administrative support for the coordination among national competent authorities in several areas, such as borderline and classification, multi-country clinical studies, derogations, vigilance and market surveillance. EMA will also provide support to SMEs.
TOPIC 6: FURTHER DIGITALISATION	
Articles	Specific provisions of the proposal
Digitalisation of compliance tools (MDR: Article 19, new Article 110a, Annex I, Annex VI, IVDR: Article 17, new Article 103a, Annex I, Annex VI)	The EU declaration of conformity may be provided in digital form. Subject to future implementing rules, certain information on the label may be provided in digital form. Manufacturers of near-patient tests will be able to provide electronic instructions for use. The submission of information pursuant to MDR/IVDR shall be performed electronically. Economic operators need to provide their digital contact in Eudamed.
Digitalisation of conformity assessment (MDR: new Article 52b, IVDR: new Article 48b)	Manufacturers may draw up technical documentation, report and other documents in digital form.
Online sales (MDR: Article 6, IVDR: Article 6)	Certain essential information necessary to identify the device and the instructions for use have to be provided in case of online sales.
UDI and Eudamed (MDR: Article 27-33, Annex VII, IVDR: Article 24-30, Annex VII)	The provisions on UDI assignment and registration in Eudamed have been clarified. It is made possible that certain electronic systems may be set up outside Eudamed.
TOPIC 7: INTERNATIONAL COOPERATION	
Articles	Specific provisions of the proposal
International cooperation and reliance mechanisms (MDR: new Article 108a and	A new section on international cooperation is introduced promoting activities aiming at

new Article 108b)	global regulatory convergence and international cooperation, such as the International Medical Device Regulators Forum (IMDRF) and the Medical Device Single Audit Programme (MDSAP).
TOPIC 8: INTERPLAY WITH OTHER UNION LEGISLATION	
Articles	Specific provisions of the proposal
Combined studies involving medicinal products, medical devices and/or IVDs (MDR: new Article 79a, IVDR: new Article 75a)	For combined studies, the sponsor may submit a single application, triggering a coordinated assessment, in accordance with Regulation (EU) No 536/2014 on clinical trials, which will be amended by the Biotech Act[28] accordingly.
Cybersecurity (MDR: new Article 87a, Annex I, IVDR: new Article 82a, Annex I)	Serious incidents reported in accordance with the vigilance system established under the MDR or IVDR, which also qualify as actively exploited vulnerabilities and severe incidents as referred to in Regulation (EU) 2024/2847 on cyberresilience, will be made available to the relevant national computer security incident response teams ('CSIRTs') and to the European Union Agency for Cybersecurity (ENISA). In addition, manufacturers will have to report actively exploited vulnerabilities and severe incidents that do not qualify as serious incidents within the meaning of the MDR or IVDR to the CSIRTs and ENISA through Eudamed. In Annex I MDR/IVDR, cybersecurity will be explicitly mentioned in the general safety and performance requirements.

Amendments to Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

[28] COM(2025)1022, see above footnote 15.

Articles	Specific provisions of the proposal
Management of expert panels (Article 30)	EMA's mandate to provide the secretariat for the medical device expert panels is aligned with changes to the provisions on expert panels in the MDR.

Amendments to (EU) 2024/1689 on artificial intelligence	
Articles	Specific provisions of the proposal
Annex I	In Annex I to the Artificial Intelligence Act, the MDR and IVDR are moved from Section A to Section B.

2025/0404 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Regulations (EU) 2017/745[3] and (EU) 2017/746[4] of the European Parliament and of the Council establish regulatory frameworks to ensure the smooth functioning of the internal market as regards medical devices and *in vitro* diagnostic medical devices, respectively, taking as a base a high level of protection of health for patients and users. At the same time, Regulations (EU) 2017/745 and (EU) 2017/746 set high standards of

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1 OJ C […], […], p. […].

2 OJ C […], […], p. […].

3 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj).

4 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176, ELI: http://data.europa.eu/eli/reg/2017/746/oj).

quality and safety for medical devices and *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, both Regulations significantly reinforce key elements of the previous regulatory framework set out in Council Directives 90/385/EEC[5] and 93/42/EEC[6] and in Directive 98/79/EC of the European Parliament and of the Council[7], such as the supervision of notified bodies, risk classification, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, and require the setting up of the European database on medical devices (Eudamed) to enable transparency and traceability in respect of medical devices and *in vitro* diagnostic medical devices.

(2) The extension of the transitional periods provided for in Article 120 of Regulation (EU) 2017/745 and Article 110 of Regulation (EU) 2017/746 mitigated the risk of shortages of medical devices and *in vitro* diagnostic medical devices in the Union, but did not address underlying structural problems related to the implementation of both Regulations.

(3) In its targeted evaluation[8] of Regulations (EU) 2017/745 and (EU) 2017/746, the Commission confirmed that the Regulations have strengthened the regulatory framework through stricter requirements on the designation and oversight of notified bodies, the conduct of conformity assessments, and the generation of clinical evidence. However, the evaluation also highlighted several shortcomings and inefficiencies in the regulatory framework, resulting in unnecessary burdens for manufacturers. Overly complex and often disproportionate requirements, costly, lenghthy and unpredictable conformity assessment procedures affect the availability of devices, the competitiveness of manufacturers in the Union, in particular of small and medium-sized enterprises, and innovation in medical technology. This has a negative impact on the level of healthcare and patient safety in the Union.

(4) To address the shortcomings identified, the existing rules should be simplified, and administrative burden should be reduced without jeopardising the high level of public health and patient safety. Moreover, the predictability and cost-efficiency of the application of both Regulations should be enhanced to achieve their initial objectives.

(5) Regulation (EU) 2017/745 includes in its scope certain groups of devices which are similar to medical devices but for which the manufacturer claims only an aesthetic or another non-medical purpose. To enhance legal certainty and to ensure consistency, it should be clarified that accessories for such products without a medical purpose are also included within the scope of Regulation (EU) 2017/745.

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5 Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17, ELI: http://data.europa.eu/eli/dir/1990/385/oj).

6 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1, ELI: http://data.europa.eu/eli/dir/1993/42/oj).

7 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, ELI: http://data.europa.eu/eli/dir/1998/79/oj).

8 SWD(2025)1051.

(6) The provisions in Regulation (EU) 2017/745 should be adapted to Regulation (EU) 2024/1938 of the European Parliament and of the Council[9], the new Union legislation in the area of substances of human origin (SoHO).

(7) To avoid a double layer of regulatory requirements, products that combine a medical device and an *in vitro* diagnostic medical device should be subject either to Regulation (EU) 2017/745 or to Regulation (EU) 2017/746, depending on the product's principal mode of action, whilst the general safety and performance requirements of the other Regulation should apply to the part of the device that has an ancillary function.

(8) The definition of nanomaterial in Regulation (EU) 2017/745 should be updated to bring it in line with Commission Recommendation of 10 June 2022 on the definition of nanomaterial[10].

(9) Clinical data are an important source of information for demonstrating the safety and performance of a device. However, the process of generating clinical data is often lengthy and costly. The definition of clinical data should be broadened to enable the use of data generated through studies on the device concerned that are published in scientific literature, but not necessarily peer-reviewed.

(10) Devices that are well-established technologies have a lower risk profile than other devices of the same risk class. They are therefore subject to certain exemptions or more proportionate requirements in Regulation (EU) 2017/745. To make the application of those provisions more flexible and future-proof, a definition of term well-established technology devices should be included in that Regulation, based on guidance developed by the Medical Device Coordination Group[11], and the existing lists of devices in Articles 18, 52 and 61 of Regulation (EU) 2017/745 should be replaced by a reference to the newly defined term.

(11) To ensure legal certainty and to safeguard the principle of free movement of goods, the coordination mechanism between national competent authorities for decisions on the regulatory status of a product and on the classification of a device, should be streamlined and, where appropriate, involve external expertise from an expert panel, supported by the European Medicines Agency (EMA). The decision on the regulatory status, however, should remain with the national authorities or, where appropriate, with the Commission acting through implementing acts.

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9 Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety of substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj).

10 Commission Recommendation of 10 June 2022 on the definition of nanomaterial, C/2022/3689 (OJ C 229, 14.6.2022, p. 1).

11 MDCG 2020-6 *Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC; A guide for manufacturers and notified bodies* (April 2020).

(12) The manufacture and use of devices within health institutions ('in-house devices') under certain conditions is essential for the provision of health care in cases where the needs of the target patient group cannot be met by devices available on the market. While the strict conditions for the exemption of such in-house devices from most of the requirements set out in Regulation (EU) 2017/745 or Regulation (EU) 2017/746 should in principle remain in place, some flexibility should be introduced in order to remove unnecessary administrative burden on health institutions, to promote clinical research on in-house devices and to enable the access of patients to in-house devices where no alternatives exist. For example, some documentation obligations should be removed, especially under Regulation (EU) 2017/746 for health institutions accredited to EN ISO 15189. The transfer of an in-house device to another health institution should be possible where justified in the interest of public health, patient health or patient safety. Also, to provide legal certainty for health institutions, when a device becomes available on the market that serves the target patient group's needs in an equivalent manner to the in-house device, the health institution should have a lengthy transition period until the exemption for in-house manufacturing ceases to apply. Due to their importance for preparedness and response to public health emergencies, the condition that no device is available on the market serving the target patient group's needs in an equivalent manner, should be removed for in-house *in vitro* diagnostic medical devices.

(13) Laboratories that conduct clinical research in the context of clinical trials of medicinal products subject to Regulation (EU) No 536/2014 often develop tests in-house to meet patient needs in clinical trials. Where those tests are not manufactured on an industrial scale and are not commercialised, the situation of such laboratory-developed tests is similar to in-house devices manufactured and used within a health institution. The exemption from certain requirements of Regulation (EU) 2017/746, as provided for in Article 5(5) of that Regulation, should therefore also apply to laboratory-developed tests used exclusively for clinical trials.

(14) To ensure a level playing field between devices sold online and those sold via traditional distribution channels, certain information requirements applicable to distance sales should be strengthened. In particular, it should be clarified that Member States may also order, on grounds of public health, the cessation of activity of providers of diagnostic or therapeutic services by way of information society services, as defined in Directive (EU) 2015/1535 of the European Parliament and of the Council[12], without prejudice to national law regulating the medical profession.

(15) While it should remain the responsibility of each Member State to determine the language in which information should be supplied to the users within their territory,

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[12] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1, ELI: http://data.europa.eu/eli/dir/2015/1535/oj).

Member States should consider accepting such information in other languages of the Union that are commonly understood in the medical field, especially regarding devices intended for professional users, in order to reduce costs for translations.

(16) To reduce complexity and enhance consistency, redundant provisions that simply state that requirements in other provisions within Regulation (EU) 2017/745 or Regulation (EU) 2017/746, or in other legislation, apply, should be removed.

(17) Some manufacturers have their devices designed and manufactured by another legal or natural person. Whilst Regulations (EU) 2017/745 and (EU) 2017/746 have increased transparency regarding the person that designs and manufactures the device, the responsibilities of the manufacturer regarding its access to the parts of the technical documentation that may be drawn up by the original equipment supplier should be clarified, also for the purpose of supervision by competent authorites.

(18) To facilitate and streamline the application of the information obligation in cases of the interruption or discontinuation of supply of certain devices as laid down in Regulations (EU) 2017/745 and (EU) 2017/746, and to enhance legal certainty regarding the devices that are subject to that information obligation, a central IT tool for the notification and information sharing should be made available. Moreover, the EMA should be empowered to draw up and publish a list of devices covered by the information obligation. The support provided by the EMA in situations of interruption or discontinuation of supply should also take into account the contribution provided by the Executive Steering Group on Shortages of Medical Devices (MDSSG) established by Regulation (EU) 2022/123 of the European Parliament and of the Council[13]. To ensure a high level of public health protection, continuous access and availability of medical devices and *in vitro* diagnostic medical devices, and to strengthen health emergency preparedness and response, Member States and the Commission should have the possibility to request manufacturers of devices, which are included in the list of devices covered by the information obligation, to provide information regarding risks and weaknesses within the supply chain that may affect the supply of such devices. That information can be used for assessing possible vulnerabilities in the supply chain of critical devices, for example within the framework of the MDSSG.

(19) Having regard to advances in digital communication and digital compliance tools and in order to reduce administrative burden, it should be specified that communication between the relevant actors and compliance with legal obligations, including the drawing up of documentation, reports and other documents as well as conformity assessment procedures should in principle be possible in digital form. Moreover, where no specific format is required, digital formats, such as electronic signatures, should be accepted by default.

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[13] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj).

(20) To simplify rules and reduce compliance costs, some overly prescriptive requirements, such as the qualification requirements for the person responsible for regulatory compliance or the permanent and continuous availability of that person when not part of the manufacturer's organisation, should be removed. Also, unnecessary reporting and certification requirements regarding the repackaging or relabelling of devices that are already placed and further distributed within the internal market, for example outside the manufacturer's official distribution schemes, should be removed.

(21) The Commission Report[14] on the operation of Article 17 of Regulation (EU) 2017/745 highlighted that the application of the rules on single-use devices is fragmented across the Union and the relevant requirements are complex to implement, resulting in a very limited and unattractive market for the reprocessing of single-use devices. To simplify the rules regarding single-use devices and to increase the re-use of devices for economic and environmental reasons, it should be the responsibility of the manufacturer to determine whether and how a device can be reprocessed, based on the device's characteristics and properties. Unless the indication of single-use is duly justified by the manufacturer, devices should be subject to reprocessing, whilst single-use devices or devices which cannot be further reprocessed should be subject to full refurbishing.

(22) The unique device identification (UDI) system and the registration of devices in the European database for medical devices (Eudamed) are fundamental tools for ensuring the traceability and transparency of devices made available on the Union market. To enhance clarity and legal certainty, the respective provisions related to those tools laid down in Regulations (EU) 2017/745 and (EU) 2017/746 should be clarified and streamlined.

(23) The use of artificial intelligence in medical devices and *in vitro* diagnostic medical devices can help foster innovation and improve diagnosis and treatment of patients. The parallel application of Regulations (EU) 2017/745 and (EU) 2017/746, as applicable, and Regulation (EU) 2024/1689[15] of the European Parliament and of the Council could lead to overlaps of requirements and stifle innovation. To prevent those overlaps and to simplify the regulatory framework for artificial intelligence-enabled devices, the application of Regulation (EU) 2024/1689 to those devices should be limited to those provisions referred to in Article 2(2) of that Regulation. The references to Regulations (EU) 2017/745 and (EU) 2017/746 in Annex I to Regulation (EU) 2024/1689 should therefore be moved from Section A to Section B. Where

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[14] Report from the Commission to the European Parliament and the Council of 29 November 2024 on the operation of Article 17 of Regulation (EU) 2017/745 of the European Parliament and the Council on single-use devices and their reprocessing (COM(2024)560 final).

[15] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).

needed, the Commission may use its implementing and delegated powers to lay down specific requirements regarding artificial intelligence, taking into account the requirements set out in Chapter III, Section 2, of Regulation (EU) 2024/1689. Moreover, notified bodies that are designated to assess high-risk AI systems falling under Regulations (EU) 2017/745 or (EU) 2017/746, as applicable, should meet also the specific AI-related requirements set out in Article 31 of Regulation (EU) 2024/1689.

(24) The summary of safety and clinical performance under Regulation (EU) 2017/745 and the summary of safety and performance under Regulation (EU) 2017/746 ensure transparency regarding the clinical evidence on which the safety and performance assessment of the device is based. As the drawing up and updating of such a summary is costly, the range of devices subject to that requirement should be clearly limited to those devices for which a systematic assessment of the device's technical documentation is required pursuant to Regulations (EU) 2017/745 and (EU) 2017/746. Moreover, the summary should be drawn up in a way that is clear for the intended user of the device. To reduce burden and enhance cost-efficiency, additional versions for other persons, such as patients, should not be required. Moreover, as the draft summary is in any case part of the documentation to be submitted to the notified body, a separate validation of the summary by the notified body should not be required. In addition, duplication of information to be provided in the summary and in the instructions for use should be avoided.

(25) In accordance with Regulations (EU) 2017/745 and (EU) 2017/746, notified bodies exercise a key function in the medical device regulatory system as the issuance of a certificate by a notified body is a prerequisite for market access of most devices. In order to ensure that devices benefit from uniform and predictable conditions for market access, the accountability of notified bodies and the degree of harmonisation of their conformity assessment activities should therefore be enhanced. For that purpose, the process for the assessment of applicant notified bodies and their designation should be streamlined. Moreover, the oversight of notified bodies should be tightened through the involvement of joint assessment teams also in the monitoring of notified bodies. In light of such changes, the full reassessment of notified bodies every five years is no longer required and should therefore be removed.

(26) To streamline the assessment and monitoring of notified bodies, the joint assessment teams should include the national authority responsible for the notified body as well as experts from other Member States and experts nominated by the Commission. Moreover, the national authority responsible for the notified body should be tasked with deciding on disputes between manufacturers and notified bodies that arise in the context of conformity assessment procedures.

(27) Even though most notified bodies are private for-profit entities, they exercise their function in the public interest. With regard to manufacturers that are micro or small

enterprises within the meaning of Commission Recommendation 2003/361/EC[16] and with regard to orphan devices, notified bodies should therefore be required to reduce their fees for conformity assessment activities in accordance with Regulations (EU) 2017/745 and (EU) 2017/746.

(28) To enhance predictability regarding the fees charged by notified bodies for conformity assessment activities of devices in accordance with Regulations (EU) 2017/745 and (EU) 2017/746 and to prevent excessively high fees, the Commission should be empowered to adopt implementing acts to set the level and structure of fees by the notified bodies, without prejudice to the potential application of Articles 101 and/or 102 of the Treaty on the Functioning of the European Union to the way notified bodies set their prices or carry out their economic activities.

(29) Devices are classified in different classes depending on their level of risk. Some of the classification rules should be adapted to reflect the inherent risk of devices, resulting in a lower risk classification, such as for reusable surgical instruments or accessories for active implantable devices.

(30) For lower and medium-risk devices, the involvement of notified bodies in the conformity assessment process should be reduced so that it is proportionate to the risk class of the device. For example, for class IIa and non-implantable class IIb devices, or most class C devices, where the notified body is to assess the technical documentation on a sampling basis, it should be clarified that the technical documentation assessment is only needed for one representative device of a category of devices or a generic device group, or in the case of class B devices only for one device from the manufacturer's product portfolio. Additional technical documentation assessment during surveillance activities should only be carried out when potential concerns exist based on data available from the post-market surveillance system. As class A sterile devices are of low risk, notified body involvement for those devices should be removed.

(31) To support innovation and the development and availability of breakthrough technology and of devices intended for small groups of patients, the conformity assessment procedures should be adapted to address the specific situation of those devices. For that purpose, criteria for breakthrough devices and orphan devices should be included in Regulations (EU) 2017/745 and (EU) 2017/746, based on guidance developed by the Medical Device Coordination Group. If the status as a breakthrough device or orphan device is confirmed by an expert panel, the review of the device by the notified body should be prioritised, if necessary with additional advice from the expert panels.

(32) The clinical evaluation consultation procedure provided for in Regulation (EU) 2017/745 is a tool to scrutinise the assessment of notified bodies regarding certain

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[16] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).

high-risk devices. The procedure should be focused on devices where that exceptional scrutiny gives an additional assurance for patient safety. The scope of the clinical evaluation consultation procedure should therefore be limited to class III implantable devices, removing from its scope class IIb active devices intended to administer and/or remove a medicinal product. However, there should be the possibility to add specific types of high-risk devices to the scope of the clinical evaluation consultation procedure by way of delegated act, where justified on grounds of patient safety.

(33) The performance evaluation assessment procedure provided for in Regulation (EU) 2017/746 is not effective for certain class D devices as it mixes up the responsibilities of expert panels and notified bodies. It should therefore be removed and replaced with an early scientific advice process for high-risk *in vitro* diagnostic medical devices that provides for the possibility of manufacturers to seek advice from expert panels on their performance evaluation strategy.

(34) When the validity of a certificate for medical devices or for *in vitro* diagnostic medical devices issued by a notified body expires, notified bodies are to assess whether the certificate can be renewed. This creates administrative burden, uncertainty and unnecessary costs. The maximum validity period of certificates issued by notified bodies should therefore be removed, unless the notified body considers it necessary to limit the validity on justified grounds, such as in the case of a certificate issued with conditions where the manufacturer has to collect additional clinical data after certification in the post-market phase, as may be the case for breakthrough technology devices.

(35) In order to respond to a public health emergency at Union level recognised in accordance with Regulation (EU) 2022/2371 of the European Parliament and of the Council[17], or to ensure the supply of medical devices and *in vitro* diagnostic medical devices falling under the definition of medical countermeasures within the framework of Council Regulation (EU) 2022/2372[18], the Commission should be able to authorise, by means of implementing acts, the placing on the market or putting into service of devices for which a conformity assessment in accordance with Regulations (EU) 2017/745 and (EU) 2017/746 has not been carried out. Moreover, where specific CE marked devices are needed, for example in greater numbers or with an adapted intended purpose, to respond to a public health emergency or a disaster or crisis, Member States, or the Commission, should be able to exempt manufacturers from certain requirements related to the manufacturing, design or intended purpose of the device.

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17 Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).

18 Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ L 314, 6.12.2024, p. 64, ELI: http://data.europa.eu/eli/reg/2022/2372/oj).

(36) To ensure that the legal framework governing the highly innovative sectors of medical devices and *in vitro* medical devices is future-proof and able to support innovation, Member States and the Commission should be able to establish regulatory sandboxes in the field of medical devices or *in vitro* diagnostic medical devices to facilitate the development and testing of innovative devices or regulatory approaches under strict oversight.

(37) Article 4 of Directive 2010/63/EU of the European Parliament and the Council[19] prescribes that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of an animal-based procedure. Non-animal tests such as New Approach Methodologies (NAMs), which include innovative *in-vitro* (cell or tissue-based), *in-chemico* (chemical-based), *in-silico* (computer-based) approaches, or combinations of these, can increasingly replace or complement animal-based tests for safety and performance studies. The use of non-animal methods, including NAMs, to provide scientific evidence in clinical and non-clinical studies should therefore be promoted.

(38) As the safety and performance of many devices other than high-risk devices can be sufficiently demonstrated using non-clinical data, including NAMs, the possibility to use non-clinical data to confirm the safety and performance of a device in the conformity assessment should therefore be made more prominent in Regulation (EU) 2017/745.

(39) Clinical data are often available for devices that are equivalent to the device under conformity assessment. In order to make the conditions under which manufacturers can claim equivalence more flexible, the requirement in Regulation (EU) 2017/745 for a contract with the manufacturer of the equivalent device granting access to its technical documentation should therefore be removed and the equivalence criteria be adapted.

(40) Post-market clinical follow-up (PMCF) is an important requirement in Regulation (EU) 2017/745 to identify any safety issues that might appear during real world use of the device. To reduce the number of reports that manufacturers are required to draw up, manufacturers should be able to include the findings of the PMCF directly in the updated clinical evaluation report, without the need to draw up a separate PMCF evaluation report.

(41) The obligation to prepare a periodic safety update report (PSUR) is an important tool provided for in Regulations (EU) 2017/745 and (EU) 2017/746 that requires manufacturers to verify the safety and performance of a device during its lifetime. In order to avoid unnecessary costs and administrative burden for manufacturers and to

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[19] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276 20.10.2010, p. 33, ELI: http://data.europa.eu/eli/dir/2010/63/2019-06-26).

make the obligation more proportionate, the frequency for updating the PSUR should be reduced depending on the risk class of the device.

(42) Unnecessary overlaps and duplication of assessments between different actors in the regulatory system negatively impact the efficiency and consistency of that regulatory system. Therefore, the roles and responsibilities of competent authorities and notified bodies, in particular regarding the assessment of vigilance cases, should be clarified and any unnecessary elements removed.

(43) There is a growing number of clinical studies involving, simultaneously, a clinical trial of a medicinal product subject to Regulation (EU) No 536/2014 of the European Parliament and of the Council[20], a performance study of an *in vitro* diagnostic medical device subject to Regulation (EU) 2017/746 or a clinical investigation of a medical device subject to Regulation (EU) 2017/745 ('combined studies'). To address concerns raised regarding the complexity of applying multiple Regulations to those combined studies, sponsors should be enabled to submit a single application for a combined study leading to its coordinated assessment under Regulation (EU) No 536/2014. Regulations (EU) 2017/746 and Regulation (EU) 2017/745 should not be applicable where a single application has been submitted.

(44) Regulation (EU) 2024/2847 of the European Parliament and of the Council[21] requires manufacturers to notify actively exploited vulnerabilities and severe incidents having an impact on the security of products with digital elements in order to ensure that the relevant national computer security incident response teams (CSIRTs) designated as coordinators, and the European Union Agency for Cybersecurity (ENISA), have an adequate overview of vulnerabilities and incidents impacting the internal market. Medical devices and *in vitro* diagnostic medical devices, however, are exempted from Regulation (EU) 2024/2847. While cybersecurity related incidents need to be reported in accordance with existing vigilance rules in Regulations (EU) 2017/745 and (EU) 2017/746 when they qualify as serious incidents, cybersecurity related incidents that do not concern public health or patient safety, are not reported. This is an important cybersecurity gap. Manufacturers of connected devices should therefore be obliged to report also those incidents to the CSIRTs and ENISA through Eudamed.

(45) The key actors under Regulations (EU) 2017/745 and (EU) 2017/746, namely manufacturers, competent authorities, notified bodies and the Commission, should have access to experts with relevant scientific, clinical, technical and regulatory expertise. Enhanced coordination and access to expertise result in a predictable and

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[20] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p.1, ELI; http://data.europa.eu/eli/reg/2014/536/oj).

[21] Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).

reliable regulatory framework. The type of expertise available in the expert panels range of areas in which expert panels provide advice and their involvement in the regulatory system set out in Regulations (EU) 2017/745 and (EU) 2017/746 should therefore be expanded. The mandate of the EMA to support the expert panels in accordance with Regulation (EU) 2022/123 should be amended accordingly.

(46) Regulations (EU) 2017/745 and (EU) 2017/746 provide for a decentralised regulatory system. Effective coordination between national authorities is essential to ensure the smooth functioning of the internal market and a coherent application of the requirements laid down in the Regulations to ensure a uniform high level of protection of patient safety and public health. For an effective and efficient coordination, national authorities need scientific, technical and administrative support, which can be provided in the most adequate way by the EMA, as it already manages the medical device expert panels. The EMA should therefore be mandated to provide, on behalf of the Commission, the necessary support for the coordination between national competent authorities to facilitate uniform application of Regulations (EU) 2017/745 and (EU) 2017/746 .

(47) The Union participates in the International Medical Device Regulators Forum (IMDRF)[22], which is a voluntary group of regulators from around the world that aims to accelerate international regulatory harmonisation and convergence in the field of medical devices and *in vitro* diagnostic medical devices. To a large extent, the Union regulatory system for medical devices reflects guidelines developed in the framework of the IMDRF. To increase efficiency, reduce duplication of regulatory efforts and promote global convergence, the Commission and Member States should actively participate in, and make use of, international regulatory cooperation and reliance mechanisms or reliance programmes.

(48) To avoid the risk of misunderstanding regarding kits that are *in vitro* diagnostic medical devices and that integrate products which are subject to other Union legislation, such as medicinal products, it should be clarified that products which are included in kits should be in conformity with the legislation applicable to those products.

(49) Regulation (EU) 2017/746 introduced specific provisions for companion diagnostics. In light of the experience gained from the application of those provisions, it is necessary to clarify in the definition of companion diagnostics that a companion diagnostic may be linked to more than one medicinal product. Moreover, to avoid any unnecessary duplication in the assessment of companion diagnostics, it should be clarified that the consultation of a medicinal products authority should only be necessary regarding novel companion diagnostics and that a consulted medicinal products authority should not repeat the assessment carried out by a notified body.

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22 International Medical Device Regulators Forum (IMDRF) | International Medical Device Regulators Forum

(50) Performance studies are an important source of clinical evidence for *in vitro* diagnostic medical devices. The rules applicable to the conduct of performance studies should be simplified in cases where they do not present any additional risks to the subjects of the study, such as in cases where the study involves routine blood draws from non-vulnerable individuals or where studies on companion diagnostics are conducted using left-over samples.

(51) The transition from the previous regulatory framework to that under Regulations (EU) 2017/745 and (EU) 2017/746 has led to the discontinuation of certain devices intended for small groups of patients, as the costs for the transition made it economically difficult for manufacturers to undertake conformity assessment in accordance with those Regulations. The discontinuation of those orphan devices jeopardises the level of care and patient protection, where no alternative diagnosis or treatment methods are available. Manufacturers should therefore be allowed, subject to certain conditions, to continue marketing orphan devices that were lawfully marketed in accordance with the Directives 90/385/EEC, 93/42/EEC and 98/79/EC without the need to conduct a conformity assessment procedure pursuant to Regulations (EU) 2017/745 and (EU) 2017/746.

(52) Certain Annexes to Regulations (EU) 2017/745 and (EU) 2017/746, which further specify the obligations and requirements applicable to notified bodies, economic operators and devices, should be aligned with the changes made in the corresponding provisions of those Regulations and to reflect the same objectives, namely simplification, burden reduction, enhanced cost-efficiency of the certification process and further digitalisation.

(53) To reduce costs and length of conformity assessment procedures for medical devices that integrate a medicinal substance or a SoHO, the consultation of the medicinal products authorities or the SoHO authorities should be streamlined and shortened. Substance-based medical devices that are systematically absorbed by the human body are medical devices. They do not incorporate any substance that, if used separately, would fall under Union legislation on medicinal products. The consultation of a medicinal products authority in the framework of the conformity assessment of such substance-based medical devices is not appropriate and should therefore be removed.

(54) Regulations (EU) 2017/745 and (EU) 2017/746 delegated to the Commission the power to adopt delegated acts in accordance with Article 290 TFEU in order to amend certain non-essential provisions in Regulations (EU) 2017/745 and (EU) 2017/746. Having regard to the experience with the application of those Regulations and the necessity to maintain a level of flexibility regarding the often very technical and procedural requirements in the Regulations, the power to adopt delegated acts should be provided also for other non-essential provisions in Regulations (EU) 2017/745 and (EU) 2017/746, to adapt them to experience gained from their application, scientific or technical progress or developments at international level.

(55) Regulations (EU) 2017/745 and (EU) 2017/746 conferred on the Commission the power to adopt implementing acts. In order to ensure uniform conditions of implementation of those Regulations additional implementing powers should be conferred on the Commission.

(56) Since the objectives of this Regulation, namely simplification and burden reduction of the rules on medical devices and on *in vitro* diagnostic medical devices, while preserving the objectives of Regulations (EU) 2017/745 and (EU) 2017/746 as such, cannot be sufficiently achieved by the Member States but can rather, by reason of the

scale or effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(57) Regulations (EU) 2017/745 and (EU) 2017/746 should therefore be amended accordingly.

(58) In order to allow all affected parties sufficient time to take the necessary measures to comply with this Regulation, the application of certain provisions should be deferred. However, provisions that do not require time for preparation should be applicable from the date of the entry into force of this Regulation.

(59) This Regulation introduces binding requirements for cross-border digital public services within the meaning of Regulation (EU) 2024/903 of the European Parliament and of the Council[23]. An interoperability assessment has therefore been completed. The Digital Dimensions chapter of the Legislative Financial and Digital Statement constitutes the resulting report,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 2017/745

Regulation (EU) 2017/745 is amended as follows:

(1) Article 1 is amended as follows:

(a) in paragraph 2, the first sentence is replaced by the following:

'This Regulation shall also apply, as from the date of application of common specifications adopted pursuant to Article 9, to the groups of products without an intended medical purpose that are listed in Annex XVI, and their accessories, taking into account the state of the art, and in particular existing harmonised standards for analogous devices with a medical purpose, based on similar technology.';

(b) paragraph 4 is replaced by the following:

'4. For the purposes of this Regulation, medical devices, accessories for medical devices, and products listed in Annex XVI and their accessories, to which this Regulation applies pursuant to paragraph 2 shall hereinafter be referred to as 'devices'.';

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[23] Regulation (EU) 2024/903 of the European Parliament and of the Council of 13 March 2024 laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act) (OJ L 2024/903, 22.3.2024, ELI: http://data.europa.eu/eli/reg/2024/903/oj).

(c) in paragraph 6, point (g) is replaced by the following:

'(g) organs intended for transplantation falling within the scope of Directive 2010/53/EU of the European Parliament and of the Council* or substances of human origin falling within the scope of Regulation (EU) 2024/1938 of the European Parliament and of the Council**, or their derivatives, or products containing or consisting of them; however, this Regulation does apply to devices manufactured utilising derivatives of substances of human origin which are non-viable or are rendered non-viable;

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* Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj).

** Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14, ELI: http://data.europa.eu/eli/dir/2010/53/oj).';

(d) paragraph 7 is replaced by the following:

'7. Any device which, when placed on the market or put into service, incorporates as an integral part an *in vitro* diagnostic medical device as defined in Article 2, point (2), of Regulation (EU) 2017/746 that has an action ancillary to that of the device in which it is incorporated, shall be governed by this Regulation. In that case, the relevant general safety and performance requirements set out in Annex I to Regulation (EU) 2017/746 shall apply with regard to the safety and performance of the *in vitro* diagnostic medical device part.

However, if the action of the *in vitro* diagnostic medical device is principal and not ancillary to that of the device in which it is incorporated, the integral product shall be governed by Regulation (EU) 2017/746. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply with regard to the safety and performance of the device part.';

(e) paragraph 10 is amended as follows:

(i) the first subparagraph is replaced by the following:

'Any device which, when placed on the market or put into service, incorporates, as an integral part, non-viable substances of human origin or their derivatives that have an action ancillary to that of the device in which they are incorporated shall be assessed and authorised in accordance with this Regulation.';

(ii) in the second subparagraph, first sentence, the reference to 'Directive 2004/23/EC' is replaced by a reference to 'Regulation (EU) 2024/1938';

(2) Article 2 is amended as follows:

(a) in point (1), the second subparagraph is replaced by the following:

‘The following products shall also be deemed to be medical devices:

– devices for the control or support of conception;

– products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4).’;

(b) point (7) is replaced by the following:

‘(7) ‘generic device group’ means a set of devices having the same or similar intended purposes and a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;’;

(c) points (18), (19), (20) and (21) are deleted;

(d) point (48) is replaced by the following:

‘(48) ‘clinical data’ means information concerning safety or performance that is generated from the use of a device and is sourced from any of the following:

– clinical investigations of the device concerned or of a device for which equivalence to the device concerned can be demonstrated;

– other studies published in scientific literature on the device concerned or of a device for which equivalence to the device concerned can be demonstrated;

– other clinical experience published in peer-reviewed scientific literature with the device concerned or a device for which equivalence to the device concerned can be demonstrated;

– clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;’;

(e) the following points (72), (73), (74), (75) and (76) are added:

‘(72) ‘well-established technology device’ means a device that belongs to a generic device group, which fulfils the following criteria:

(a) it has simple, common and stable design;

(b) it has not been associated with safety issues in the past;

(c) it has well-known clinical performance characteristics and comprises standard of care devices with little evolution in indications and the state of the art;

(d) it has a long history on the Union market;’;

(73) ‘combined study’ means a clinical trial, as defined in Article 2(2), point (2), of Regulation (EU) No 536/2014, of one or more medicinal products, combined with a performance study of one or more *in vitro* diagnostic medical devices as defined in Article 2, point (42), of Regulation (EU) 2017/746, and/or with a clinical investigation of one or more devices;

(74) ‘regulatory sandbox’ means a controlled environment set up by a competent authority which offers manufacturers or prospective manufacturers the possibility to develop, test, validate and use, where appropriate in real-world conditions, an innovative product or technology

potentially falling within the scope of this Regulation, pursuant to a sandbox plan for a limited time under regulatory supervision;

(75) 'sandbox plan' means a document agreed between the participating manufacturer(s) or prospective manufacturer(s) and the competent authority describing the objectives, conditions, timeframe, methodology and requirements for the activities carried out within the regulatory sandbox;

(76) 'Union regulatory sandbox' means a controlled environment set up by the Commission for testing alternative or new regulatory requirements or enforcement practices and appraising their validity in comparison with existing requirements and practices under this Regulation for a limited time.';

(3) Articles 3 and 4 are replaced by the following:

'Article 3

Amendment and implementation of certain definitions

1. The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend the definition of well-established technology device set out in Article 2, point (72), in the light of technical and scientific progress and taking into account definitions agreed at Union and international level.

2. The Commission may, by means of implementing acts, draw up non-exhaustive lists of devices that fall under, or of devices that do not fall under the definition of well-established technology device in Article 2, point (72).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 4

Regulatory status of products

1. The competent authorities of the Member States shall coordinate their activities when determining whether a specific product, or category, or group of products, falls within the definition of 'medical device' set out in Article 2, point (1), or the definition of 'accessory for a medical device' set out in Article 2, point (2), or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex.

2. The Member States shall ensure an appropriate level of consultation of the relevant competent authorities of the Member States in the fields of *in vitro* diagnostic medical devices, medicinal products, substances of human origin (SoHO), biocides, food products, cosmetics or other products subject to Union legislation, where the determination of whether a product has the regulatory status of a device involves aspects concerning the borderline with any of those types of products. If that is the case, Member States shall also ensure an appropriate level of consultation of the relevant advisory or regulatory bodies established in the relevant Union legislation, such as the European Medicines Agency (EMA), the SoHO Coordination Board, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA).

3. Where a competent authority of a Member State, after having performed an evaluation in accordance with Article 94, considers that a product that is CE marked in accordance with Article 20, does not fall within the scope of this Regulation, it shall consult the competent authorities of the other Member States regarding its envisaged measure determining the regulatory status of the product in question.

4. Where a competent authority of a Member State raises a substantiated disagreement regarding the envisaged measure referred to in paragraph 3, the consulting authority shall refer the matter to an expert panel as referred to in Article 106 and give utmost consideration to the opinion of that expert panel.

5. The results of the coordination activities of the competent authorities in accordance with this Article and the opinions of the expert panel delivered in accordance with paragraph 4 of this Article and Article 4a(2) shall be made publicly available, without disclosing any confidential information as referred to in Article 109.

6. The Commission may, by means of implementing acts, lay down the procedure, including timelines, for the application of paragraphs 1 to 4 of this Article and of Article 4a. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

(4) the following Article 4a is inserted:

'Article 4a

Opinion on and determination of the regulatory status of a product

1. A competent authority, a notified body, a manufacturer, a developer of a product or the Commission may submit a substantiated request for an opinion from an expert panel referred to in Article 106 on the question whether a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory for a medical device', or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex. Where, in such a request, the requester considers that the product in question is a device, the request shall also specify the proposed classification of the device in accordance with Article 51 and Annex VIII.

2. The expert panel shall provide its opinion without undue delay. The requester shall give utmost consideration to the opinion of the expert panel.

3. Having regard to the expert panel opinion referred to in paragraph 2 or in Article 4(4), a Member State may submit a substantiated request to the Commission to determine whether a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory for a medical device', or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex.

The Commission shall decide on the substantiated request of the Member State or on its own initiative, by means of implementing acts, which shall be adopted in accordance with the examination procedure referred to in Article 114(3).

The Commission may ask the expert panel for clarifications or refer the opinion back to the expert panel for further consideration, including in cases

where a Member State's substantiated request raises new questions of a scientific or technical nature.

4. This Article shall not apply where within the framework of another Union legislation the regulatory status of the product, or category or group of products concerned has been determined as falling within the scope of that other Union legislation, or where a procedure for the determination of the regulatory status is ongoing within the framework of another Union legislation.';

(5) Article 5 is amended as follows:

(a) paragraph 5 is amended as follows:

(i) the first subparagraph is amended as follows:

(1) point (a) is replaced by the following:

'(a) the devices are not transferred to another legal entity, except to another health institution in the duly justified interest of public health, patient safety or patient health, or to prepare or respond to a public health emergency;';

(2) point (d) is replaced by the following:

'(d) upon request by a competent authority, the health institution provides information upon request on the use of such devices, which includes the justification referred to in points (a) and (c);';

(3) point (f) is replaced by the following:

'(f) the health institution draws up documentation that is sufficiently detailed to enable the competent authority to ascertain that the relevant general safety and performance requirements set out in Annex I are met;';

(4) point (g) is deleted;

(ii) the second subparagraph is replaced by the following:

'Member States shall retain the right to restrict the manufacture or the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.';

(iii) The following three subparagraphs are added:

'For the purposes of the first subparagraph, point (a), in the case of a transfer of the device to another health institution, the transferring and receiving health institutions shall ensure traceability of the device.

For the purposes of the first subparagraph, point (c), from the date that the health institution becomes aware that the target patient group's specific needs can be met by a device available on the market, it may continue to manufacture and use its device for a maximum period of 10 years.

For the purposes of the first subparagraph, point (h), where the device is transferred in accordance with point (a), the receiving health institution shall report any incident related to the device to the transferring health institution.';

(b) the following paragraphs 7 and 8 are added:

‘7. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the general safety and performance requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies.

8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council***, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation.

*** Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).’;

(6) Article 6 is amended as follows:

(a) the following paragraph 2a is inserted:

‘2a. Any natural or legal person offering a device in accordance with paragraph 1 or a service in accordance with paragraph 2 shall provide in the offer at least the information referred to in Annex I, Section 23.2, points (a) to (d) and (m), and access to the instructions for use.’;

(b) paragraphs 3 and 4 are replaced by the following:

‘3. Upon request by a competent authority, any natural or legal person offering a device in accordance with paragraph 1 or a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity drawn up in accordance with Article 19 or the statement drawn up in accordance with Article 21(2) for the device concerned and cooperate with the competent authorities of the Member State where the device or the service is offered.

4. A Member State may, on grounds of protection of public health, require a provider of a service as defined in Article 1(1), point (b), of Directive (EU) 2015/1535, or a provider of a service in accordance with paragraph 2, to cease its activity.’;

(7) in Article 7, the following subparagraph is added:

‘Without prejudice to national law regarding the exercise of the medical profession, the first subparagraph shall also apply to devices used for the provision of a service referred to in Article 6(2).’;

(8) in Article 9(1), the first sentence is replaced by the following:

‘Where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG, may, by means of implementing acts, adopt common specifications (CS) in respect of the requirements set out in this Regulation, in particular the reports and plans to be drawn up by manufacturers, the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III, the conformity assessment procedures set out in Annexes IX to XI and the procedure for custom-made devices set out in Annex XIII, the clinical evaluation and post-market clinical follow-up set out in Annex XIV or the requirements regarding clinical investigation set out in Annex XV.’;

(9) Article 10 is amended as follows:

(a) paragraphs 3 and 7 are deleted;

(b) paragraph 9 is replaced by the following:

‘9. Manufacturers shall put in place an appropriate quality management system to ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in device design or characteristics and changes in the harmonised standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner. Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device.

The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation.’;

(c) paragraph 10 is deleted;

(d) in paragraph 11, the following subparagraph is added:

‘When determining the official language of the Union in which the information set out in Section 23 of Annex I or other information to be provided by the manufacturer shall be made available, Member States shall consider accepting another official language of the Union in which the information is made available, taking into consideration the technical knowledge, experience, education or training of the average intended user(s).’;

(e) paragraph 13 is deleted;

(f) paragraph 14 is amended as follows:

(i) the third subparagraph is deleted;

(ii) the fourth subparagraph is deleted;

(g) paragraph 15 is replaced by the following:

‘15. Where manufacturers have their devices designed and manufactured by another legal or natural person, the information on the identity of that person shall be part of the information to be submitted in accordance with Article 29(4). In those cases, the manufacturer shall ensure that the relevant parts of the technical documentation are drawn up, kept up to date and, upon request, made available to the competent authorities in accordance with paragraphs 4 and 8 of this Article by the legal or natural person that has designed and manufactured the device. In addition, the manufacturer shall draw up, keep up to date and, upon request, make available to the competent authorities the remaining parts of the technical documentation, in particular those referred to in Section 2 of Annex II and in Annex III.’;

(h) paragraph 16 is deleted;

(10) Article 10a is amended as follows:

(a) in paragraph 1, the second subparagraph is replaced by the following:

‘The information referred to in the first subparagraph shall be provided at least six months before the anticipated interruption or discontinuation or, if this is not possible, without undue delay after the manufacturer becomes aware of the anticipated interruption or discontinuation. The manufacturer shall specify the reasons for the interruption or discontinuation in the information provided to the competent authority.’;

(b) the following paragraphs 4, 5 and 6 are added:

‘4. The Commission, where needed in cooperation with the EMA, shall set up, maintain, and manage an IT system to facilitate the reporting and information exchange regarding cases of interruption or discontinuation of the supply of devices in accordance with paragraphs 1, 2 and 3. That IT system shall be integrated in or interoperable with the European database on medical devices referred to in Article 33. It shall also enable health institutions and healthcare professionals to inform competent authorities about the unavailability or the immediate risk of unavailability of devices needed for the exercise of their professional activity.

5. The EMA, in collaboration with the Executive Steering Group on Shortages of Medical Devices (MDSSG) established by Article 21 of Regulation (EU) 2022/123, shall develop a methodology to identify the devices, or categories of devices, for which it is reasonably foreseeable that an interruption or discontinuation of supply could result in serious harm or a risk of serious harm to patients or public health as referred to in paragraph 1. Based on that methodology, the EMA, in collaboration with the MDSSG and in agreement with the Commission, shall draw up, publish and keep up to date a list of devices, or categories of devices, to which paragraphs 1, 2 and 3 shall apply. For the purpose of this paragraph, the MDCG, representatives of manufacturers, other relevant actors in the supply chain for the medical device sector and representatives of healthcare professionals, of patients and of consumers may be consulted as necessary.

6. The competent authorities of the Member States or the Commission may request the manufacturers of devices included in the list drawn up in

accordance with paragraph 5 to provide all necessary information regarding risks and weaknesses within the supply chain which may affect the supply of such devices, including production capacity and volume of sales.';

(11) in Article 11, paragraphs 4 and 5 are deleted;

(12) in Article 14, paragraph 2 is amended as follows:

(a) in the first subparagraph, point (d) is replaced by the following:

'(d) that, where applicable, a UDI has been assigned by the manufacturer in accordance with Article 27(3).';

(b) the second subparagraph is replaced by the following:

'In order to meet the requirements referred to in the first subparagraph, the distributor may apply a sampling method that is representative of the devices supplied by that distributor.';

(13) Article 15 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices.';

(b) paragraph 2 is replaced by the following:

'2. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC**** shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person at their disposal.

****Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).';

(c) in paragraph 3, point (c) is replaced by the following:

'(c) the post-market surveillance obligations are complied with in accordance with Article 83;';

(d) paragraph 6 is replaced by the following:

'6. Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements or medical devices in the Union.';

(14) Article 16 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, the introductory wording is replaced by the following:

‘A distributor, an importer or another natural or legal person who places a product on the market or puts it into service shall assume the obligations incumbent on manufacturers if it does any of the following:’;

(ii) the second subparagraph is replaced by the following:

‘The first subparagraph shall not apply to any healthcare professional or any other person who, while not considered a manufacturer, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.’;

(b) paragraph 4 is deleted;

(15) Article 17 is replaced by the following:

‘Article 17

Single-use devices and reprocessing of devices that are not for single use

1. A device shall only be intended for single-use where the manufacturer, in light of the design, construction, material, chemical, physical and biological properties of the device, cannot ensure that the device continues to meet the relevant safety and performance requirements when reused in accordance with its intended purpose after appropriate reprocessing. The manufacturer’s justification of an indication of single use shall be part of the technical documentation referred to in Annex II.

2. If the device is not intended for single-use, the manufacturer shall provide information about the appropriate reprocessing process for allowing reuse in the instructions for use in accordance with Annex I, Section 23.4, point (n).

3. Single-use devices and devices that cannot be further reprocessed may be subject to full refurbishing within the meaning of Article 2(31). The natural or legal person that carries out the full refurbishing shall be considered as the manufacturer of the fully refurbished device.

4. The Commission may adopt, in accordance with Article 9(1), CS on general requirements regarding reprocessing of devices or fully refurbishing of single-use devices.’;

(16) Article 18 is amended as follows:

(a) in paragraph 1, second subparagraph, the first sentence is replaced by the following:

‘The information referred to in the first subparagraph shall be provided, for the purpose of making it available to the patient who has been implanted with the device, by any means, including in electronic or digital format, that allow rapid access to that information and shall be stated in the language(s) determined by the concerned Member State.’;

(b) paragraph 3 is replaced by the following:

‘3. Implants that are well-established technology devices shall be exempted from the obligations laid down in this Article’;

(17) in Article 19, the following paragraph 2a is inserted:

‘2a. Declarations of conformity in accordance with paragraphs 1 and 2 may be provided in electronic form.’;

(18) in Article 22, paragraph 2 is replaced by the following:

‘2. The statement made pursuant to paragraph 1 shall contain at least the following information:

(a) an identification of the devices and, where applicable, other products included in the system or procedure pack, including where applicable their Basic UDI-DI;

(b) where applicable, an identification of the notified body involved in the sterilisation activities referred to in paragraph 3;

(c) a declaration by the natural or legal person that:

(i) they have verified the mutual compatibility of the devices and, if applicable, other products in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions;

(ii) they have packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;

(iii) the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.’;

(19) Article 27 is amended as follows:

(a) in paragraph 1, after point (b) the following point (ba) is inserted:

‘(ba) a Basic UDI-DI, as defined in Part C of Annex VI;’;

(b) paragraph 2 is amended as follows:

(i) point (d) is replaced by the following:

‘(d) the entity gives access to its system for the assignment of UDIs to all interested users in accordance with a set of predetermined and transparent terms and conditions that take into account the interests of micro, small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC;’;

(ii) in point (e), the following point (iv) is added:

‘(iv) offer its system for the assignment of UDIs to manufacturers that are micro and small enterprises within the meaning of Recommendation 2003/361/EC under preferential conditions that take into account the specific needs of such enterprises and are proportionate to their size.’;

(c) paragraph 3 is replaced by the following:

‘3. Before placing a device, other than a custom-made device or investigational device, on the market, the manufacturer shall, in accordance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2, assign to the device a Basic

UDI-DI and a UDI as defined in Part C of Annex VI. If applicable, the manufacturer shall assign a UDI-DI to all higher levels of packaging.';

(d) the following paragraphs 3a and 3b are inserted:

'3a. Before placing on the market a system or procedure pack pursuant to Article 22(1) and (3), the natural or legal person responsible shall assign to the system or procedure pack, in accordance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2, a Basic UDI-DI and UDI as defined in Part C of Annex VI.

3b. For devices that are the subject of a conformity assessment as referred to in Article 52(3) and in Article 52(4), second and third subparagraphs, a Basic UDI-DI referred to in paragraph 1 of this Article shall be assigned before the manufacturer applies to a notified body for that assessment.';

(e) in paragraph 10, points (a) and (b) are replaced by the following:

'(a) amending the list of information set out in Parts A and B of Annex VI in the light of technical progress;

(b) amending Annex VI in the light of experience obtained from the implementation of the UDI system, or in the light of international developments and technical progress in the field of Unique Device Identification.';

(f) in paragraph 11, the following point (c) is added:

'(c) determining the UDI related obligations laid down in this Article, Article 29 and Annex VI Part C that shall not apply to certain devices, categories or groups of devices in view of the highly individualised characterisation of those devices, or in view of their risk class, the number of devices placed on the market and the financial and administrative burden related to the assignment of UDI.'.

(20) Article 28 is amended as follows:

(a) paragraph 3, is replaced by the following:

'3. The core data elements to be provided to the UDI database, referred to in Part B of Annex VI, shall be accessible to the public, except the element referred to in point 13 of that Part.'.

(21) Article 29 is replaced by the following:

'Article 29

Registration of devices and systems or procedure packs

1. Before placing a device, other than a custom-made device or investigational device, on the market, the manufacturer shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device, as applicable. The manufacturer shall keep the information provided to the UDI database updated.

2. Before placing on the market a system or procedure pack as referred to in Article 22(1) and (3), the natural or legal person responsible shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that system or procedure pack. The

natural or legal person referred to in Article 22(1) shall keep up to date the information provided to the UDI database.

3. For devices that are the subject of a conformity assessment as referred to in Article 52(3) and in Article 52(4), second and third subparagraphs, the notified body shall confirm in Eudamed that the information referred to in Part B of Annex VI is correct.';

(22) Article 30 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The Commission, after consulting the MDCG, shall set up and manage an electronic system to create the single registration number referred to in Article 31(2) and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative, the importer and the person referred to in Article 22(1). The details regarding the information to be provided to that electronic system by the economic operators are laid down in Part A, Section 1, of Annex VI.';

(b) in paragraph 2, the following sentence is added:

'Where national distributor databases require information on devices, such databases shall allow for the retrieval of the device information from the electronic systems referred to in Article 33(2), points (a) and (b).';

(23) Article 31 is amended as follows:

(a) the title is replaced by the following:

'**Registration of economic operators**';

(b) paragraphs 1 and 2 are replaced by the following:

'1. Before placing a device, other than a custom-made device, on the market, manufacturers, authorised representatives, importers and persons referred to in Article 22(1) of this Regulation shall, in order to register, submit to the electronic system referred to in Article 30 the information referred to in Part A of Annex VI, provided that they have not already registered in accordance with this Article. In cases where the conformity assessment procedure requires the involvement of a notified body pursuant to Article 52, the information referred to in Part A of Annex VI shall be provided to that electronic system before applying to the notified body.

2. Without undue delay, the competent authority shall verify the data entered pursuant to paragraph 1, obtain a single registration number ('SRN') from the electronic system referred to in Article 30 and issue it to the manufacturer, the authorised representative, the importer or the person referred to in Article 22(1).';

(c) in paragraph 4, the words 'one week' are replaced by the words 'two weeks';

(d) paragraph 6 is deleted;

(e) paragraph 7 is replaced by the following:

'7. The data entered pursuant to paragraph 1 of this Article in the electronic system referred to in Article 30 shall be accessible to the public, except

the information regarding the person responsible for regulatory compliance referred to in Part A, point 1.4, of Annex VI.';

(f) paragraph 8 is replaced by the following:

'8. The competent authority may use the data to charge the manufacturer, the authorised representative, the importer or the person referred to in Article 22(1) a fee pursuant to Article 111.';

(24) Article 32 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. For class IIb implantable devices and for class III devices, other than custom-made or investigational devices and well-established technology devices, the manufacturer shall draw up a summary of safety and clinical performance.

The summary of safety and clinical performance shall be written in a way that is clear to the intended user and shall be made available to the public via Eudamed.

The draft of the summary of safety and clinical performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 52. The manufacturer shall ensure that the summary of safety and clinical performance is available in Eudamed as part of the information on the device to be provided pursuant to Article 29(1) and mention on the label or instructions for use where that summary is available.';

(b) in paragraph 2, point (h) is replaced by the following:

'(h) information on any residual risks or undesirable effects, and any warnings and precautions.';

(25) Article 33 is amended as follows:

(a) in paragraph 2, the following subparagraph is inserted:

'By way of derogation from the first subparagraph, the Commission may decide that one or more of the electronic systems referred to in that subparagraph are not to be included in Eudamed. In that case, the Commission shall ensure that those electronic systems are interoperable with Eudamed.';

(b) paragraph 3 is replaced by the following:

'3. When designing Eudamed and, where applicable, any of the electronic systems that are not included in Eudamed, the Commission shall give due consideration to compatibility with national databases and national web-interfaces to allow for import and export of data.';

(c) paragraph 4 is replaced by the following:

'4. The data shall be entered into Eudamed and, where applicable, any of the electronic systems that are not included in Eudamed by the Member States, notified bodies, economic operators and sponsors as specified in the provisions on the electronic systems referred to in paragraph 2. The Commission shall provide for technical and administrative support to users of Eudamed and, where applicable, any of the electronic systems that are not included in Eudamed.';

(d) paragraph 5 is replaced by the following:

‘5. All the information collated and processed by Eudamed and, where applicable, any of the electronic systems that are not included in Eudamed shall be accessible to the Member States and to the Commission. The information shall be accessible to notified bodies, economic operators, sponsors and the public to the extent specified in the provisions on the electronic systems referred to in paragraph 2.

The Commission shall ensure that public parts of Eudamed and, where applicable, any of the electronic systems that are not included in Eudamed, are presented in a user-friendly and easily-searchable format.’;

(e) paragraph 6 is replaced by the following:

‘6. Eudamed and, where applicable, any of the electronic systems that are not included in Eudamed, shall contain personal data only insofar as necessary for the electronic systems to collate and process information in accordance with this Regulation. Personal data shall be kept in a form which permits identification of data subjects for periods no longer than those referred to in Article 10(8).’;

(f) Paragraph 8 is replaced by the following:

‘8. The Commission shall, by means of implementing acts, lay down the detailed arrangements necessary for the setting up and maintenance of Eudamed and, where applicable, any of the electronic systems that are not included in Eudamed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). When adopting those implementing acts, the Commission shall ensure that, as far as possible, the systems are developed in such a way as to avoid having to enter the same information twice within the same electronic system or in different electronic systems.’;

(g) paragraph 9 is replaced by the following:

‘9. In relation to its responsibilities under this Article and the processing of personal data involved therein, the Commission shall be considered to be the controller of Eudamed and its electronic systems as well as, where applicable, any of the electronic systems that are not included in Eudamed.’;

(26) Article 34(1) is replaced by the following:

‘1. The Commission shall, in collaboration with the MDCG, draw up the functional specifications for Eudamed and, where applicable, any of the electronic systems that are not included in Eudamed.’.

(27) Article 35 is amended as follows:

(a) the following paragraph 6a is inserted:

‘6a. Without prejudice to other administrative or judicial remedies, a manufacturer or notified body may raise with the authority responsible for notified bodies, in a duly substantiated manner, any unresolved dispute arising from the application of the requirements set out in Annex VII and the involvement of a notified body in the conformity assessment in accordance with Article 52 and Annexes IX, X and XI. The authority

shall hear and decide within 90 days. Where the manufacturer is established in another Member State than the notified body, the authority responsible for the notified body shall consult the competent authority of the Member State where the manufacturer is established.

In duly justified cases, the authority responsible for notified bodies may seek guidance from the MDCG, which it shall take duly into account.

Each authority responsible for notified bodies shall inform the Commission and the MDCG at least annually about the disputes raised with it pursuant to the first subparagraph, their outcome and the parties involved. That information shall be taken into consideration in the framework of the monitoring of notified bodies in accordance with Article 44.

By way of derogation from the first subparagraph and without prejudice to other administrative or judicial remedies, a Member State may choose to assign the tasks set out in this paragraph to another authority or to an out of court dispute resolution body.';

(b) paragraph 8 is replaced by the following:

'8. The authorities responsible for notified bodies shall coordinate their activities to be carried out in accordance with this Chapter, cooperate with each other and with the Commission and resolve issues of diverging opinions between themselves to ensure a harmonised application of the requirements relating to notified bodies.';

(28) Article 36 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Notified bodies shall fulfil the tasks for which they are designated in accordance with this Regulation in the public interest. They shall satisfy the organisational and general requirements and the quality management, resource and process requirements, as set out in further detail in Annex VII, that are necessary to fulfil those tasks in an effective, independent, diligent and expeditious manner.

Notified bodies designated for conformity assessment activities relating to devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, or that use high-risk AI systems as safety components, shall also meet the requirements set out in Article 31(4), (5), (10) and (11) of that Regulation.';

(b) the following paragraph 4 is added:

'4. The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend Annex VII in order to adapt to technical or scientific progress regarding conformity assessment in the field of medical devices, including developments at international level.';

(29) in Article 37, paragraph 4 is deleted;

(30) Article 39 is replaced by the following:

‘Article 39

Assessment of the application

1. The authority responsible for notified bodies shall within 30 days check that the application referred to in Article 38 is complete and shall request the applicant to provide any missing information. Once the application is complete, that authority shall send it to the Commission.

2. Within 14 days of the receipt of the application referred to in paragraph 1 of this Article, the Commission, in consultation with the MCDG, shall appoint three experts, chosen from the list referred to in Article 40(2). In view of the specific circumstances of the application, a different number of experts may be appointed.

   At least one of the experts shall be an expert representing the Commission. The other experts shall be experts nominated by Member States other than the one in which the applicant conformity assessment body is established.

   In order to be chosen in accordance with the first subparagraph, the experts shall be competent to assess the conformity assessment activities and the types of devices which are the subject of the application.

3. The experts appointed in accordance with paragraph 2 and the authority responsible for notified bodies shall form a joint assessment team that shall be coordinated by the expert representing the Commission.

4. Within 90 days of the appointment of the experts in accordance with paragraph 3, the joint assessment team shall review the application and supporting documentation and shall draw up a preliminary assessment report. During that period, the joint assessment team may request any clarifications from the applicant conformity assessment body. The joint assessment team shall submit the preliminary assessment report to the applicant conformity assessment body.

5. Where, based on the review of the application and supporting documentation referred to in this paragraph, the joint assessment team considers that the applicant body does not and, within a reasonable period of time, will not be able to meet the requirements of this Regulation and that any further assessment in accordance with paragraphs 6 to 9 is not appropriate, it shall draw up a final assessment report and the authority responsible for the notified bodies shall reject the application.

6. Unless the application is rejected, the joint assessment team shall plan and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or subcontractor, located inside or outside the Union, that is to be involved in the conformity assessment process.

   Where an on-site assessment of the applicant body, a subsidiary or a subcontractor is temporarily impossible or impracticable due to exceptional circumstances, the joint assessment team may decide to carry out the assessment by other appropriate means.

   At the end of the on-site assessment, the joint assessment team shall list for the applicant conformity assessment body any non-compliances resulting from the assessment and summarise the assessment by the joint assessment team.

7. Within 30 days after the finalisation of the on-site assessment, the joint assessment team shall submit the assessment report to the applicant conformity assessment body and, where applicable, inform that body about any non-compliances resulting from the assessment.

   Where the joint assessment team has not identified any non-compliances, its assessment report shall be considered the final assessment report and paragraph 11 shall apply.

8. Where the joint assessment team has identified non-compliances, the applicant conformity assessment body shall submit to the joint assessment team a proposed corrective and preventive action plan to address the non-compliances effectively and in a timely manner.

   That plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions therein.

9. Within 30 days of receipt of the proposed corrective and preventive action plan referred to in paragraph 8, the joint assessment team shall assess whether the non-compliances identified during the assessment have been appropriately addressed and, where necessary, provide any comments on it to the applicant conformity assessment body, including requests for further clarification and modifications.

   The applicant conformity assessment body and the joint assessment team shall endeavour to agree on a final corrective and preventive action plan in due course.

10. Within 30 days of receipt of the final corrective and preventive action plan, or of the moment the joint assessment team concludes that no agreement on a final plan has been reached, the joint assessment team shall draw up its final assessment report. That report shall include the result of the assessment, conclusions regarding the corrective and preventive action plans and whether the non-compliances have been appropriately addressed and, where applicable, the recommended scope of designation.

11. The joint assessment team shall submit its final assessment report to the MCDG without undue delay.

    Based on the findings of the final assessment report, the authority responsible for notified bodies shall submit to the MDCG a draft decision on the designation of the notified body or reject the application.

12. Within 21 days of receipt of the draft decision on the designation referred to in paragraph 11, the MDCG shall issue a recommendation with regard to the envisaged designation, which the authority responsible for notified bodies shall duly take into consideration for its final decision on the designation of the notified body. That 21-day period may be extended once for a further 21 days on justified grounds.

13. Where the authority responsible for notified bodies does not agree with the recommendation of the MDCG, it shall submit to the MDCG a duly justified request to reconsider its recommendation. Within 30 days of receipt of that request, the MDCG shall either confirm its recommendation or issue a new recommendation.

14. Where no agreement can be reached between the MDCG and the authority responsible for notified bodies, either party may refer the matter to the Commission.

Within 180 days of receipt of the referral, the Commission shall, after consulting the MDCG, the authority responsible for notified bodies and, where necessary, the applicant conformity assessment body concerned, evaluate the draft decision on the designation and decide, by means of implementing act, whether or not the draft designation is justified.

15. If, at any stage of the process, consensus cannot be reached within the joint assessment team on any issue, any member of the joint assessment team may refer the issue to the MDCG, which shall provide its views without undue delay and at the latest within 60 days from the referral.

16. The Commission may, by means of implementing acts, adopt measures setting out detailed arrangements specifying the procedures and any relevant documentation for the following:

(a) the application for designation referred to in Article 38;

(b) the assessment of the application set out in this Article;

(c) the nomination and selection of experts referred to in Article 40;

(d) the monitoring of notified bodies pursuant to Article 44.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

(31) Article 40 is amended as follows:

(a) the title is replaced by the following:

'***Nomination of experts for joint assessment'***;

(b) paragraph 1 is replaced by the following:

'1. All Member States that have appointed an authority responsible for notified bodies and the Commission shall nominate experts who are qualified in the assessment, designation or monitoring of conformity assessment bodies in the field of medical devices or in the assessment of manufacturers' technical documentation and who will be available to participate in the activities referred to in Articles 39, 44 and 48. Member States that have not appointed an authority responsible for notified bodies may nominate experts who have those qualifications.

The nominated experts shall commit to participate in joint assessments.';

(32) the following Article 40a is inserted:

'*Article 40a*

Funding of activities related to designation and monitoring of notified bodies

1. Conformity assessment bodies and notified bodies shall pay a fee for the assessment of their application for designation and their monitoring, including the costs for the involvement of experts nominated in accordance with Article 40 in those assessment and monitoring activities.

2. The structure and level of the fees and the scale and type of recoverable costs shall be established by the Commission by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

(33) the third paragraph of Article 41 is replaced by the following:

'The applicant shall provide translations of the documentation pursuant to Articles 38 and 39, or parts thereof, into an official Union language, such as is necessary for that documentation to be readily understood by the joint assessment team referred to in Article 39(4).';

(34) Article 42 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Member States may only designate conformity assessment bodies in accordance with the recommendation of the MDCG issued in accordance with Article 39(11) or (12) or in accordance with an implementing act adopted by the Commission in accordance with Article 39(14).';

(b) paragraph 4 is replaced by the following:

'4. The notification shall be accompanied by the recommendation of the MDCG.';

(c) paragraphs 6 to 9 are deleted;

(d) paragraph 10 is replaced by the following:

'10. When publishing the notification in NANDO, the Commission shall add to the electronic system referred to in Article 57 the information relating to the notification of the notified body along with the documents referred to in paragraph 4 of this Article.';

(35) Article 44 is amended as follows:

(a) the title is replaced by the following:

'**Monitoring of notified bodies**';

(b) in paragraph 2, the second sentence is replaced by the following:

'Notified bodies shall, upon request by their authority responsible for notified bodies, supply all relevant information and documents required to enable the authority and the joint assessment team to verify compliance.';

(c) the following paragraph 3a is inserted:

'3a. The authority responsible for notified bodies shall conduct its monitoring and assessment activities in accordance with an assessment programme considering the full scope of the notified body's activities. That programme shall ensure that the authority can effectively monitor the continued compliance of the notified body with the requirements of this Regulation and shall provide a reasoned schedule for the frequency of assessment of the notified body and, where applicable, its subsidiaries and/or subcontractors for a period of at least two years. The authority responsible for notified bodies shall submit the programme for monitoring or assessment for each notified body for which it is responsible to the MDCG and to the Commission. The authority shall

address any request for clarification or modification made by the Commission or the MDCG.';

(d) paragraph 4 is replaced by the following:

'4. At least once a year, the authorities responsible for notified bodies shall assess whether each notified body established on their respective territory and, where appropriate, the subsidiaries and subcontractors under the responsibility of those notified bodies still satisfy the requirements and fulfil their obligations set out in this Regulation, in particular Annex VII.

Where necessary, the assessment shall include an on-site audit of the notified body, its subsidiaries or subcontractors.

The authority, the MDCG or the Commission may request the participation of experts from the Commission and other Member States in the annual assessment of a notified body.';

(e) the following paragraphs 4a, 4b and 4c are inserted:

'4a. At least every two years, the annual assessment of a notified body shall be carried out by a joint assessment team including the authority responsible for notified bodies and two experts from the list referred to in Article 40(2) appointed by the Commission in consultation with the MDCG. At least one of those experts shall be an expert representing the Commission. In light of the specific circumstances of the monitoring, the Commission may appoint a different number of experts. The joint assessment team shall be coordinated by the expert representing the Commission.

If, at any stage of the process, consensus cannot be reached within the joint assessment team on any issue, any member of the joint assessment team may refer the issue to the MDCG, which shall provide its views without undue delay and at the latest within 60 days from the referral.

4b. At the end of any assessment carried out pursuant to paragraph 4 or 4a, the authority responsible for notified bodies or the joint assessment team, as applicable, shall inform the notified body about any non-compliances resulting from the assessment and summarise their assessment.

Where non-compliances have been identified, the notified body shall submit a proposed corrective and preventive action plan to address the non-compliances. That plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions set out therein.

The authority responsible for notified bodies or the joint assessment team, as applicable, shall assess whether the non-compliances identified during the assessment have been appropriately addressed in the plan referred to in the second subparagraph and, where necessary, provide any comments on the plan to the notified body, including requests for further clarification and modifications. The notified body and the authority or the joint assessment team, as applicable, shall endeavour to agree on a final corrective and preventive action plan in due course.

4c. After receipt of the final corrective and preventive action plan, or where the authority responsible for notified bodies or the joint assessment team,

as applicable, have not identified non-compliances or conclude that no agreement on a final plan has been reached, the authority or the joint assessment team, as applicable, shall draw up their final monitoring report which shall include the result of the assessment and, where applicable, conclusions regarding the corrective and preventive action plan and, where applicable, any recommendations regarding the notified body's designation.

The authority responsible for notified bodies or the joint assessment team, as applicable, shall submit their final monitoring report to the MDCG without undue delay.

The authority responsible for notified bodies shall monitor the implementation of the corrective and preventive action plan by the notified body, as appropriate.

Where the final monitoring report concludes that the notified body no longer meets the requirements set out in this Regulation, or where the notified body fails to implement the corrective and preventive action plan, the authority responsible for notified bodies shall follow the procedure set out in Article 46(4).';

(f) paragraph 5 is replaced by the following:

'5. The monitoring of notified bodies shall include observed audits of notified body personnel, including where necessary any personnel from subsidiaries and subcontractors, as that personnel is in the process of conducting quality management system assessments at a manufacturer's facility.';

(g) in paragraph 6, the first subparagraph is replaced by the following:

'The monitoring of notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance.';

(h) paragraph 8 is replaced by the following:

'8. During the monitoring of a notified body, an appropriate number of the notified body's assessments of manufacturers' quality management system and technical documentation, in particular the clinical evaluation documentation, shall be reviewed either off-site or on-site. The sampling of files shall be representative of the types and risk of devices certified by the notified body, in particular high-risk devices. ';

(i) paragraphs 9, 10 and 11 are deleted;

(j) paragraph 12 is replaced by the following:

'12. The authority responsible for notified bodies shall draw up an annual summary of their monitoring activities regarding notified bodies and, where applicable, subsidiaries and subcontractors. That summary shall be made publicly available through the electronic system referred to in Article 57.';

(36) Article 45 is deleted;

(37) Article 46 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

‘1. The authority responsible for notified bodies shall notify the Commission and the MDCG of any application for relevant changes to the designation of a notified body.

The procedures set out in Articles 39 and 42 shall apply to significant extensions of the scope of the designation. By way of derogation from Article 39, an on-site assessment shall not be conducted where the Joint Assessment Team considers such assessment not to be necessary for the assessment of the requested scope extension.

For changes to the designation other than significant extensions of its scope, the procedures laid down in paragraphs 2 to 9 shall apply.

2. After having assessed the application for changes, the authority responsible for notified bodies shall notify the Commission of the relevant changes to the designation. The Commission shall without undue delay publish the amended notification in NANDO. The Commission shall also, without undue delay, enter information on the changes to the designation of the notified body in the electronic system referred to in Article 57.’;

(b) in paragraph 4, the first subparagraph is replaced by the following:

‘Where an authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in this Regulation or that it is failing to fulfil its obligations or has not implemented the necessary corrective measures, the authority shall suspend, restrict, or fully or partially withdraw the designation or impose conditions on the notified body, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period.’;

(38) Article 47 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The Commission, in conjunction with the MDCG, shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body, or of one or more of its subsidiaries or subcontractors, of the requirements set out in this Regulation. It shall ensure that the relevant authority responsible for notified bodies is informed and is given an opportunity to investigate those concerns.’;

(b) paragraph 3 is replaced by the following:

‘3. The Commission, in consultation with the MDCG, may initiate the assessment by a joint assessment team as referred to in Article 39(2) to (10), where there is reasonable concern about the ongoing compliance of a notified body, or a subsidiary or subcontractor of the notified body, with the requirements set out in the Regulation and where the investigation by the authority responsible for notified bodies is not deemed to have fully addressed the concerns or upon request of the authority responsible for notified bodies. The reporting and outcome of that assessment shall follow the principles set out in Article 39.’;

(39) Article 48 is amended as follows:

(a) the title is replaced by the following:

'***Exchange of experience between authorities responsible for notified bodies'***;

(b) paragraphs 2 to 5 are deleted;

(40) Articles 49 and 50 are replaced by the following:

'Article 49

Coordination of notified bodies

1. The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of a coordination group of notified bodies in the field of medical devices, including *in vitro* diagnostic medical devices. The coordination group shall meet on a regular basis, at least annually, and report to the MDCG.

   The Commission may establish the specific arrangements for the functioning of the coordination group.

2. Notified bodies shall ensure that their specialised personnel participate in the relevant activities of the coordination group.

3. All bodies notified under this Regulation and under Regulation (EU) 2017/746 shall actively participate in the work of the coordination group to support the implementation of this Regulation and of Regulation (EU) 2017/746 by sharing experience and developing common templates and technical guidance to facilitate harmonisation and common approaches regarding conformity assessment activities. They shall cooperate with each other, with the Commission, with the relevant authorities of the Member States, with expert panels and, where applicable, expert laboratories or European Union reference laboratories to ensure a harmonised application of the requirements set out in this Regulation and in Regulation (EU) 2017/746.

4. All bodies notified under this Regulation and under Regulation (EU) 2017/746 shall adhere to a code of conduct developed by the coordination group and approved by the MDCG. The code of conduct shall set out the principles of public interest, highest professional competence and integrity, impartiality, independence, transparency, proportionality, predictability and accountability to which notified bodies commit when exercising the rights and obligations conferred on them by this Regulation or Regulation (EU) 2017/746.

Article 50

Access to notified bodies and fees

1. Notified bodies shall establish lists of their fees for the conformity assessment activities that they carry out and shall make those lists publicly available. They shall notify the lists to the Commission, which shall make references to them available to the public on a dedicated website.

2. Notified bodies shall apply at least a 50 % fee reduction for manufacturers that are micro enterprises within the meaning of Recommendation 2003/361/EC and at least a 25 % fee reduction for small enterprises within the meaning of that Recommendation. They shall apply at least a 50 % fee reduction for manufacturers that apply for conformity assessment of an orphan device

referred to in Article 52a(3). Notified bodies shall provide manufacturers that are micro or small enterprises within the meaning of Recommendation 2003/361/EC the possibility to defer the payment of fees until the relevant conformity assessment activity is finalised.

3. The Commission, in consultation with the MDCG, may adopt implementing acts to specify the structure and level of the fees referred to in paragraph 1, taking into account the need to:

   (a) establish and maintain high standards of quality and safety of devices;

   (b) ensure the availability of devices;

   (c) protect the interests of micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC;

   (d) support innovation and competitiveness.

4. Notified bodies shall ensure that manufacturers, which are micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC, have access to their conformity assessment activities in a manner that is not less favourable than the manner in which access is provided to other manufacturers.

5. Notified bodies shall deal with any request for conformity assessment activities from a manufacturer and, within 15 days of receipt of the request, inform the manufacturer accordingly.

6. When duly justified in the interest of public health or patient health or safety, the authority responsible for notified bodies may instruct a notified body to accept a manufacturer's request for conformity assessment activities falling within that notified body's scope of designation.';

(41) Article 51 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. The competent authorities shall coordinate their activities when determining the classification of a device, or a category or group of devices. The results of the coordination activities of the competent authorities, including the results of any decision or measure adopted by a competent authority in accordance with Articles 51a or 51b and any opinion issued by an expert panel in relation to classification, shall be made publicly available, without disclosing any confidential information as referred to in Article 109.';

(b) in paragraph 3, point (b) is replaced by the following:

'(b) that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII, taking into consideration the principle of proportionality and classification of devices at international level.';

(c) in paragraph 5, the first sentence is replaced by the following:

'In order to ensure the uniform application of the rules set out in Annex VIII, and taking account of the relevant scientific opinions of the relevant

scientific committees or expert panels, the Commission is empowered to adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.';

(d) the following paragraph 7 is added:

'7. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend Annex VIII in order to adapt it to technical or scientific progress or to take into account developments regarding classification of devices at international level.';

(42) the following Articles 51a and 51b are inserted:

'Article 51a

Classification in the event of a dispute between manufacturer and notified body

1. A manufacturer or a notified body may refer any dispute between them arising from the application of Annex VIII to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State in which the authorised representative referred to in Section 2.2, second paragraph, point (b), last indent, of Annex IX has its registered place of business.

2. Within 30 days of receipt of the referral referred to in paragraph 1, the competent authority shall consult the other Member States regarding its draft classification decision.

3. Where, within 30 days of receipt of the consultation referred to in the paragraph 2, no substantiated disagreement has been raised by a Member State, the competent authority shall adopt its decision within 90 days of receipt of the referral referred to in paragraph 1.

4. Where, within 30 days of receipt of the consultation referred to in paragraph 2, a substantiated disagreement has been raised by a Member State regarding the draft classification decision, the matter shall be referred to an expert panel as referred to in Article 106. That expert panel shall deliver an opinion on the classification of the device within 30 days. The competent authority may ask the expert panel for clarifications on its opinion.

5. Within 30 days of receipt of the expert panel opinion, or any requested clarification, referred to in paragraph 4, the competent authority shall adopt its decision, giving utmost consideration to the expert panel opinion. It shall notify the other Member States and the Commission of its decision without undue delay.

6. The Commission may, by means of implementing acts, lay down further details of the procedure for the application of this Article and of Article 51b. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 51b

Challenges to the classification of CE marked devices

1. Where a competent authority, after having performed an evaluation in accordance with Article 94, considers that a device that is CE marked in accordance with Article 20, is not classified in accordance with Annex VIII, it shall consult the other Member States regarding its envisaged measure on the classification of the device.

2. Where, within 30 days of receipt of the consultation referred to in paragraph 1, no substantiated disagreement is raised by a Member State, the competent authority may adopt the measure on the classification of the device in question and shall notify the other Member States and the Commission of its decision giving the reasons for the decision.

3. Where, within 30 days of receipt of the consultation referred to in paragraph 1, a substantiated disagreement is raised by a Member State regarding the envisaged measure on the classification, the matter shall be referred to an expert panel referred to in Article 106, which shall deliver an opinion on the classification of the device within 30 days. The competent authority may ask the expert panel for clarifications on its opinion.

4. The competent authority shall give utmost consideration to the expert panel opinion. Where the competent authority adopts a measure on the classification, it shall notify the other Member States and the Commission of its measure without undue delay.';

(43) Article 52 is amended as follows:

(a) in paragraph 3, the following subparagraph is added:

'By way of derogation from the first subparagraph, class III devices that are well-established technology devices shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation of one representative device per generic device group.';

(b) paragraph 4 is replaced by the following:

'4. Manufacturers of class IIb devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation of one representative device per generic device group or, in the case of non-implantable class IIb devices that are well-established technology devices, one representative device per each category of devices.

By way of derogation from the first subparagraph, for class IIb implantable devices, except well-established technology devices, the assessment of the technical documentation as specified in Section 4 of Annex IX shall apply for every device. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex X coupled with a conformity assessment based on product conformity verification as specified in Annex XI. ';

(c) paragraph 5 is deleted;

(d) paragraph 6 is replaced by the following:

‘6. Manufacturers of class IIa devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, including an assessment of the technical documentation of one representative device for each category of devices.

Alternatively, the manufacturer may choose to draw up the technical documentation set out in Annexes II and III coupled with a conformity assessment as specified in Section 10 or Section 18 of Annex XI. The assessment of the technical documentation shall apply for one representative device for each category of devices.’;

(e) paragraph 7 is amended as follows:

(i) the second sentence is replaced by the following:

‘If those devices are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, the manufacturer shall apply the procedures set out in Chapters I and III of Annex IX, or in Section 10a of Annex XI’;

(ii) the following subparagraph is added:

‘Where the manufacturer of class I reusable surgical instruments has applied harmonised standards or CS covering all relevant aspects referred to in the first subparagraph, point (c), the involvement of a notified body is not required.’;

(f) paragraph 12 is replaced by the following:

‘12. The documents relating to the procedures referred to in paragraphs 1 to 7 shall be available in any official Union language acceptable to the notified body.’;

(g) in paragraph 14, the first subparagraph is replaced by the following:

‘The Commission may, by means of implementing acts, specify detailed arrangements and procedural aspects for any of the following aspects:

(a) the basis for the selection of the representative device for the assessment of the technical documentation as referred to in paragraphs 3, 4 and 6;

(b) the modalities of unannounced on-site audits and sample tests to be conducted by notified bodies in accordance with Section 3.4 of Annex IX, taking into account the risk-class and the type of device,

(c) the physical, laboratory or other tests to be carried out by notified bodies in the context of sample tests, assessment of the technical documentation and type examination;

(d) the modalities of the conformity assessment procedures regarding breakthrough devices and orphan devices set out in Article 52a;’;

(h) the following paragraph 15 is added:

‘15. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend Annexes IX, X, XI and XIII in order to adapt to technical or scientific progress or to developments regarding conformity assessment of devices at international level and to take into

account the needs of particular devices in view of their special characteristics.';

(44) the following Articles 52a and 52b are inserted:

'Article 52a

Conformity assessment of breakthrough devices and of orphan devices

1. For the conformity assessment of breakthrough devices and orphan devices, for which a notified body is involved in the conformity assessment, the procedures laid down in Article 52 shall apply subject to the specific arrangements set out in this Article.

2. A device shall be considered a breakthrough device if it meets the following criteria:

   (a) it is expected to introduce in the Union a high degree of novelty with respect to the device technology, related clinical procedure or the application of the device in clinical practice;

   (b) it is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following:

      (i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art;

      (ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.

3. A device shall be considered an orphan device if it meets the following criteria:

   (a) it is intended for the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12 000 individuals in the Union per year;

   (b) at least one of the following criteria is met:

      (i) there are insufficient available alternatives;

      (ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art, taking into account both device-specific factors and patient population-specific factors.

4. Upon a duly substantiated request by a manufacturer or a notified body, an expert panel referred to in Article 106 shall provide an opinion as to whether the criteria set out in paragraph 2 or 3 of this Article, as applicable, are fulfilled. That opinion shall be published on a dedicated website without disclosing any confidential information as referred to in Article 109 and shall be duly taken into consideration by the manufacturer and the notified body.

5. Where the opinion of the expert panel confirms the fulfilment of the criteria set out in paragraph 2 or 3 of this Article, the manufacturer of a breakthrough device or of an orphan device, as applicable, may request advice from the expert panels referred to in Article 106 regarding its clinical development strategy and appropriate preclinical or clinical data for the clinical evaluation of the device.

6. For a confirmed breakthrough device or an orphan device, as applicable, the notified body involved in the conformity assessment procedure set out in Article 52 shall prioritise the conformity assessment of that device and apply, where appropriate, a rolling review with a view to reduce assessment timelines.

   The notified body shall give due consideration to an opinion or advice provided by the expert panels in accordance with paragraph 4 or 5 and, where it does not follow such opinion or advice, it shall provide duly justified reasons. The notified body may ask the expert panel to clarify the opinion it has provided.

7. The notified body shall issue a certificate pursuant to Article 56 where the pre-market clinical evidence, even if based on limited clinical data, is deemed adequate, provided that either of the following conditions is fulfilled:

   (a) the benefit of the immediate availability on the market of the device outweighs the risk associated with the fact that additional clinical data are still required;

   (b) the benefit-risk-ratio of the device is favourable and the manufacturer commits to providing additional data from post-market clinical follow-up activities.

   Where appropriate, the notified body shall limit the validity of the certificate and specify any conditions for or limitations to the certificate's validity in accordance with Article 56, such as a requirement for the manufacturer to conduct specific post-market clinical follow-up activities within a specified period of time.

8. The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend this Article to adapt to technical or scientific progress or to take into account developments regarding conformity assessment of breakthrough devices or orphan devices at international level.

9. The Commission may, by means of implementing acts, lay down further details of the procedure for the conformity assessment of breakthrough devices or orphan devices set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 52b

Digitalisation of technical documentation, conformity assessment and reports

1. The manufacturer may draw up and make available in a digital format the technical documentation and any reports or other documents required pursuant to this Regulation. That digital format may be a structured machine-readable format, provided that it is possible to transform it into human-readable format, and that there is version-control to enable the conduct of retrospective conformity checks. Where the technical documentation, reports or other documents are to be submitted to and assessed by a notified body, the manufacturer shall agree with the notified body on the digital format.

2. Where necessary to ensure that the digital format referred to in paragraph 1 is reliable, interoperable and standardised, the Commission may establish minimum requirements or functional specifications for the digital format by means of common specifications as referred to in Article 9.';

(45) in Article 53, paragraph 5 is replaced by the following:

‘5. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities in the public interest and_with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.’;

(46) Articles 54 and 55 are replaced by the following:

‘Article 54

Clinical evaluation consultation procedure for certain high-risk devices

1. In addition to the procedures applicable pursuant to Article 52, a notified body shall follow the procedure regarding clinical evaluation consultation as specified in Section 5.1 of Annex IX or as referred to in Section 6 of Annex X, as applicable, when performing a conformity assessment of class III implantable devices, other than custom-made devices.

   Where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend paragraph 1 in order to add other types of devices to those devices that are subject to the clinical evaluation consultation procedure referred to in the first subparagraph.

2. By way of derogation from paragraph 1, the procedure referred to in that paragraph is not required in the following cases:

   (a) for a renewal of a certificate issued under this Regulation;

   (b) where the device has been designed by modifying a device already marketed for the same intended purpose, provided that the manufacturer has demonstrated to the satisfaction of the notified body that the modifications do not adversely affect the benefit-risk ratio of the device;

   (c) where the principles of the clinical evaluation of the device type or category have been addressed in a harmonised standard referred to in Article 8 or in CS referred to in Article 9 and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant harmonised standard or CS for clinical evaluation of that kind of device.

3. The notified body shall notify the competent authorities, the authority responsible for notified bodies and the Commission through the electronic system referred to in Article 57 of whether or not the procedure referred to in paragraph 1 of this Article is to be applied. That notification shall be accompanied by the clinical evaluation assessment report.

4. The notified body shall give utmost consideration to the opinion issued by the expert panel in the framework of the clinical evaluation consultation procedure. Where the notified body has not followed the views and recommendations expressed in that opinion, it shall provide a substantiated justification of the reasons therefore and its final clinical evaluation assessment report to the

authority responsible for notified bodies of the Member State in which it is established, to the expert panel that issued the opinion and to the Commission.

Article 55

Mechanism for scrutiny of conformity assessments

1. The MDCG or the Commission may, based on reasonable concerns, request advice from an expert panel in relation to the safety and performance of any device. For that purpose, the MDCG or the Commission may request the notified body that issued the certificate for the device in question to submit to the expert panel its clinical evaluation assessment report and any subsequent surveillance assessment reports regarding that device. The expert panel may request the notified body or the manufacturer to submit additional information needed for its assessment.

2. The MDCG or the Commission may, based on reasonable concerns, request advice from one or more expert laboratories, based on laboratory testing, in relation to the safety and performance of any device, provided that the device falls within the scope of designation of those expert laboratories. For that purpose, the MDCG or the Commission may request the notified body that issued the certificate for the device in question to submit to the expert laboratories its clinical evaluation assessment report and any subsequent surveillance assessment reports regarding that device. The expert laboratories may request the notified body or the manufacturer to submit samples of the device or any additional information needed for their assessment.

3. The notified body shall give utmost consideration to the advice provided by the expert panel or the expert laboratory and, where needed, take any appropriate measures, including those referred to in Article 56(3) and (4).';

(47) Article 56 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

'1. The notified bodies shall issue certificates in accordance with Annexes IX, X and XI in an official Union language and immediately upload them in Eudamed. The minimum content of the certificates shall be as set out in Annex XII.

2. The validity of certificates shall not be limited in time, unless in exceptional cases where the notified body considers it necessary to limit the period of validity based on duly justified grounds. In those cases, the notified body shall indicate the period of validity on the certificate. If the period of validity of the certificate is limited, on application by the manufacturer, the notified body may, following an assessment performed in accordance with Annex VII, Section 4.11, extend the validity of the certificate. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.'

(b) the following paragraph 2a is inserted:

'2a. During the validity of the certificate, the notified body shall carry out appropriate surveillance activities, including periodic reviews taking into consideration developments of the state of the art. Those reviews shall be proportionate to the risk class of the device.';

(c) paragraph 3 is replaced by the following:

‘3. Notified bodies may impose conditions on the validity of the certificate, such as limiting the intended purpose of a device to certain groups of patients or requiring the manufacturer to undertake specific PMCF studies pursuant to Part B of Annex XIV.’;

(d) in paragraph 4, the first sentence is replaced by the following:

‘Where a notified body finds that the requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any conditions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body.’;

(e) in paragraph 5, the first sentence is replaced by the following:

‘The notified body shall enter in the electronic system referred to in Article 57 any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and conditions imposed on certificates.’;

(48) Article 57 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) point (f) is replaced by the following:

‘(f) the notifications for conformity assessments and information or documents referred to in Article 54(3) and (3a);’;

(ii) point (i) is deleted;

(49) Article 59 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. By way of derogation from Article 52 and on a duly justified request, any competent authority may authorise for a limited period of time the placing on the market or putting into service within the territory of the Member State concerned of a specific device for which the applicable conformity assessment procedures have not been carried out, provided that the use of that device is in the interest of public health, patient safety or patient health.’;

(b) the following paragraph 1a is inserted:

‘1a. By way of derogation from Article 6(2) and on a duly justified request, any competent authority may authorise for a limited period of time the provision of a diagnostic or therapeutic service referred to in that Article to a natural or legal person established within the territory of the Member State concerned using a device for which the applicable conformity assessment procedures set out in this Regulation have not been carried out, provided that the provision of that service is in the interest of public health, patient safety or patient health.’;

(c) paragraph 2 is replaced by the following:

‘2. The Member State shall inform the Commission, the other Member States and the relevant expert panels referred to in Article 106 of any decision to authorise the placing on the market or putting into service of a device, or the provision of a service, in accordance with paragraph 1 or 1a, where such authorisation is granted for use other than for a single patient.

The Member State shall also make information about such authorisations publicly available.’;

(d) in paragraph 3, the first subparagraph is replaced by the following:

‘3. Where a request pursuant to paragraph 1 or paragraph 1a has been submitted to competent authorities in more than one Member State and based on an opinion of an expert panel referred to in Article 106, the Commission, in exceptional cases relating to public health, patient safety or patient health, may, by means of implementing acts, extend for a limited period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 or paragraph 1a to the territory of the Union, or provide an authorisation referred to in paragraph 1 or paragraph 1a for the territory of the Union. The Commission may set out the conditions under which the device may be placed on the market or put into service, or under which the diagnostic or therapeutic service may be provided. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).’;

(e) the following paragraphs 4 and 5 are added:

‘4. In the event of a public health emergency at Union level recognised in accordance with Article 23 of Regulation (EU) 2022/2371 of the European Parliament and of the Council*****, the Commission may, by means of implementing acts, on its own initiative after consulting the MDCG, authorise the placing on the market or putting into service of a device in accordance with paragraph 3. The authorisation shall cease to apply at the latest when the recognition of the public health emergency is terminated pursuant to Article 23(2) of Regulation (EU) 2022/2371. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 114(4).

5. The Commission may, by means of implementing acts, lay down rules further specifying the procedure set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).’;

***** Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).’;

(50) the following Articles 59a, 59b and 59c are inserted:

'Article 59a

Derogations from certain requirements in the event of a serious cross-border threat to health, disaster or crisis

1. Upon a duly justified request by the manufacturer, a competent authority may authorise for a limited period of time, by way of derogation from the relevant provisions in Annexes II, III, IX, X and XI, an exemption from the requirements related to changes to the manufacturing, design or intended purpose of a CE marked device, where it is in the interest of public health, patient safety or patient health, in either of the following circumstances:

   (a) a serious cross-border threat to health as defined in Article 3, point (1), of Regulation (EU) 2022/2371;

   (b) a disaster or a crisis within the meaning of Regulation (EU) …/… of the European Parliament and of the Council******[+].

2. The manufacturer shall ensure that the manufactured devices remain in conformity with the relevant general safety and performance requirements set out in Annex I.

3. The competent authority may request the notified body that issued a certificate for the device in question, to assist it in the assessment of a request referred to in paragraph 1.

4. Where applicable, the manufacturer shall keep the notified body that issued a certificate for the device in question, informed about any changes made regarding the manufacturing, design or intended purpose of a CE marked device in accordance with the authorisation referred to in paragraph 1.

5. Where a request pursuant to paragraph 1 has been submitted to competent authorities in more than one Member State, the Commission, in exceptional cases relating to public health, patient safety or patient health, may, by means of implementing acts, extend for a limited period of time the validity of an exemption granted by a Member State in accordance with paragraph 1 to the territory of the Union, or provide an exemption referred to in paragraph 1 for the territory of the Union. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

[+] OJ: Please insert in the text the number of the Regulation contained in 2025/0223(COD) (Proposal for a Regulation on the Union Civil Protection Mechanism and Union support for health emergency preparedness and response, and repealing Decision No 1313/2013/EU) and insert the number, date, title and OJ reference of that Regulation in the footnote.

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 114(4).

****** Regulation (EU) .../... of the European Parliament and of the Council of ... on ... (OJ ..., ELI).

Article 59b

Regulatory sandboxes at national level

1. Member States, on their own initiative or upon a substantiated request by a manufacturer or a prospective manufacturer, may establish one or more regulatory sandboxes to which the application of certain requirements of Chapters V or VI or of Annexes I, VIII IX, X, XI, XIV or XV would not be appropriate. The Member States shall designate the competent authority that is responsible for the supervision of the regulatory sandbox.

   Member States may also establish regulatory sandboxes jointly with other Member States.

2. The activities within a regulatory sandbox shall take place pursuant to a specific sandbox plan that shall clearly identify the requirements of this Regulation referred to in paragraph 1, which, by way of derogation from this Regulation, are temporarily adapted or waived in the regulatory sandbox, a justification that the application of those requirements is considered not appropriate and an explanation as to how potential risks related to the adaptation or waiver are controlled and mitigated. The plan shall also identify the reasonable duration of the regulatory sandbox necessary to achieve its objectives and the participants in the regulatory sandbox and their respective roles.

3. A regulatory sandbox shall be set up only if the following conditions are met:

   (a) the device is expected to address unmet medical needs or to provide a significant clinical benefit to patients or to the health system compared with similar existing alternatives or the state of the art;

   (b) the application of the requirements of this Regulation referred to in paragraph 1 would impede or significantly delay the development of the device and access by healthcare professionals or lay users to such device.

4. The Member State may request an expert panel referred to in Article 106 to provide scientific, technical or regulatory advice on the draft sandbox plan.

5. Any participant in the regulatory sandbox shall, without undue delay, inform the competent authority that is responsible for the supervision of the regulatory sandbox about any harm occurred in relation to the implementation of the regulatory sandbox. The competent authority shall take immediate and adequate corrective measures, including to suspend, revoke or restrict the scope of the regulatory sandbox.

6. Manufacturers and prospective manufacturers participating in a regulatory sandbox shall remain liable under applicable Union and national law for any

damage inflicted on third parties as a result of their activities taking place in the regulatory sandbox.

7. The Member State shall inform the Commission and the MDCG about the establishment of a regulatory sandbox and keep them informed about its implementation and outcome.

Article 59c

Union regulatory sandboxes

1. The Commission, on its own initiative or upon a substantiated request by a Member State, may establish, by means of implementing acts for a limited time and pursuant to a specific plan, Union regulatory sandboxes, which shall inform whether the existing requirements appropriately regulate a specific type of device with particular characteristics or emerging technologies, and there is a risk that the existing requirements:

   (a) would impede or significantly delay the development of such devices and access by healthcare professionals or lay users to those devices; or

   (b) would not adequately protect the health and safety of patients, users or other persons or other aspects of public health.

   Union regulatory sandboxes shall not involve the placing on the market or putting into service of devices which do not comply with this Regulation.

2. The Commission shall request an expert panel as referred to in Article 106 to provide scientific, technical or regulatory advice on the design of a Union regulatory sandbox.

3. The Commission shall inform the MDCG about the establishment of a regulatory sandbox and keep it informed about its outcome.

4. The Commission may, by means of implementing acts, specify common principles or the detailed arrangements for the establishment, operation and supervision of regulatory sandboxes pursuant to Article 59b or of Union regulatory sandboxes pursuant to this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

5. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this Article or Article 59b in order to adapt it to scientific, technical or regulatory progress and to take into account developments regarding regulatory sandboxes, including in areas other than medical devices.';

(51) in Article 60, the following paragraphs 1a and 1b are inserted:

'1a. The person referred to in Article 22(1) or (3) may request the competent authority of the Member State where it is established to issue a certificate of free sale for a system or procedure pack for which it has drawn up a statement in accordance with Article 22.

1b. The competent authority shall make the certificates of free sale issued in accordance with paragraphs 1 and 1a publicly available in Eudamed.';

(52) Article 61 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

‘1. Manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and with Part A of Annex XIV to confirm the safety and performance of the device under normal conditions of use in accordance with the intended purpose of the device, and shall evaluate any undesirable side-effects and the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I.

The manufacturer shall specify and justify the level of clinical evidence necessary to confirm the safety and performance of the device. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose, taking into consideration paragraph 10.

The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report as referred to in Section 4 of Annex XIV, which, except for custom-made devices, shall be part of the technical documentation referred to in Annex II relating to the device concerned.

2. For class IIb and class III devices, a manufacturer may, prior to its clinical investigation or clinical evaluation, consult an expert panel as referred to in Article 106, with the aim of reviewing the manufacturer's intended clinical development strategy or proposals for clinical investigation. The manufacturer and the notified body involved in any future conformity assessment procedure shall, in the clinical evaluation report and the clinical evaluation assessment report, give due consideration to the advice of the expert panel and where they do not follow the advice, they shall provide duly justified reasons.’;

(b) in paragraph 4, first subparagraph, the introductory wording is replaced by the following:

‘In the case of implantable class IIb devices and class III devices, other than custom-made devices, clinical investigations shall be performed, except if:’;

(c) paragraph 5 is replaced by the following:

‘5. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by it, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the original clinical evaluation has been performed in compliance with the requirements of this Regulation and the manufacturer provides clear evidence thereof to the notified body.’;

(d) paragraph 6 is amended as follows:

(i) the introductory wording is replaced by the following:

‘The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable class IIb devices and class III devices:’;

(ii) point (b) is replaced by the following:

‘(b) that are well-established technology devices for which the clinical evaluation is based on sufficient clinical evidence and is in

compliance with the relevant product-specific CS, where such CS are available.';

(e) paragraph 8 is deleted;

(f) paragraphs 10 and 11 are replaced by the following:

'10. Without prejudice to paragraph 4, where the confirmation of safety and performance based on clinical data is not deemed appropriate, adequate justification shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer and the data available for the generic device group. In such a case, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing, *in vitro*, *ex vivo*, *in silico* testing, computational modeling or simulation and pre-clinical evaluation, to be adequate.

11. The clinical evaluation, its documentation and, where applicable and needed, the summary of safety and performance referred to in Article 32 shall be updated throughout the life cycle of the device concerned with data and findings obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84, whenever those data and findings obtained from PMCF provide information relevant for the confirmation of safety and performance of the device.'

(g) paragraph 12 is deleted;

(h) the following paragraph 14 is added:

'14. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend Annex XIV in order to adapt it to technical and scientific progress and developments at international level, having due regard to the protection of the health and safety of patients, users or other persons and other aspects of public health.';

(53) in Article 62, the introductory wording is replaced by the following:

'Clinical investigations shall be designed, authorised, conducted, recorded and reported in accordance with the provisions of this Article, of Articles 63 to 73 and of Articles 75 to 80, the acts adopted pursuant to Article 81, and Annex XV, where they are carried out to assess an investigational device that has not been placed on the market or put into service in accordance with this Regulation and where carried out for one or more of the following purposes:';

(54) in Article 64(1), point (g) is replaced by the following:

'(g) there are scientific grounds for expecting that participation in the clinical investigation will produce either of the following:

(i) a direct benefit to the incapacitated subject outweighing the risks and burdens involved;

(ii) a benefit for the population represented by the incapacitated subject provided that the clinical investigation poses only minimal risk to, and imposes minimal burden on, the incapacitated subject in comparison with the standard treatment of the subject's condition.';

(55) in Article 65, point (g) is replaced by the following:

'(g) there are scientific grounds for expecting that participation in the clinical investigation will produce either of the following:

(i) a direct benefit to the minor subject outweighing the risks and burdens involved;

(ii) a benefit for the population represented by the minor subject provided that the clinical investigation will pose only minimal risk to, and will impose minimal burden on, the minor subject in comparison with the standard treatment of the subject's condition.';

(56) in Article 66, point (a) is replaced by the following:

'(a) the clinical investigation has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved, or if the clinical investigation has not the potential to produce such direct, the following conditions are met:

(i) a clinical investigation of comparable effectiveness cannot be carried out on women who are not pregnant or breastfeeding;

(ii) the clinical investigation contributes to the attainment of results capable of benefitting pregnant or breastfeeding women or other women in relation to reproduction, or other embryos, foetuses or children;

(iii) the clinical investigation poses a minimal risk to, and imposes a minimal burden on, the pregnant or breastfeeding woman concerned, her embryo, foetus or child after birth;';

(57) in Article 68(1), point (b) is replaced by the following:

'(b) there are scientific grounds to expect that participation of the subject in the clinical investigation will have the potential to produce either of the following:

(i) a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering and/or improving the health of the subject, or in the diagnosis of its condition;

(ii) a benefit for the population represented by the subject provided that the clinical investigation will pose only minimal risk to, and will impose minimal burden on, the subject in comparison with the standard treatment of the subject's condition;';

(58) in Article 72, the following paragraph 7 is added:

'7. The processing of personal data in the context of a clinical investigation, including the secondary use of personal data initially collected for other investigations, shall be deemed to be carried out for scientific research purposes as referred to in Article 9(2), point (j), of Regulation (EU) 2016/679.';

(59) in Article 74, paragraph 1 is replaced by the following:

‘1. Where a clinical investigation is to be conducted to further assess, within the scope of its intended purpose and in accordance with its PMCF plan, a device which already bears the CE marking in accordance with Article 20(1), (‘PMCF investigation’), and where the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic system referred to in Article 73. The sponsor shall include the documentation referred to in Chapter II, Sections 1, 3 and 4, of Annex XV as part of the notification. Article 62(4), points (b) to (k) and (m), Article 75(1), Articles 76 and 77, Article 80(5) and (6), and the relevant provisions of Annex XV shall apply to PMCF investigations involving additional invasive or burdensome procedures.;

(60) Article 75 is amended as follows:

(a) in paragraph 1, the first sentence is replaced by the following:

‘If a sponsor intends to introduce modifications to a clinical investigation that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation, it shall notify, by means of the electronic system referred to in Article 73, the Member State(s) in which the clinical investigation is being or is to be conducted of the reasons for and the nature of those modifications.’;.

(b) paragraph 2 is replaced by the following:

‘2. Where the clinical investigation has been the subject of an authorisation in accordance with Article 62(4), point (a), the Member State shall assess any substantial modification to the clinical investigation in accordance with the procedure laid down in Article 71.’;

(c) in paragraph 3, the introductory wording is replaced by the following:

‘The sponsor may implement the modifications referred to in paragraph 1 as soon as the Member State concerned has notified the sponsor of its authorisation or, where there is no authorisation, at the earliest 38 days after the notification from the sponsor referred to in that paragraph, unless:’;

(61) Article 78 is amended as follows:

(a) in paragraph 4, the second subparagraph is replaced by the following:

‘The final assessment report shall be taken into account by all Member States concerned when deciding on the sponsor's application in accordance with paragraph 11.’;

(b) paragraph 5 is replaced by the following:

‘5. Each Member State concerned may request, on a single occasion, additional information from the sponsor. The sponsor shall submit the requested additional information within 12 days of receipt of the request. The expiry of the last deadline pursuant to paragraph 4, point (d), shall be suspended from the date of the request until such time as the additional information has been received.’;

(c) in paragraph 6, the reference to ‘50 days’ is replaced by ‘20 days’;

(d) the following paragraph 15 is added:

'15. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this Article in light of experience gained from the practical application of the coordinated assessment procedure, in particular as regards timelines and the authorisation of clinical investigations subject to a coordinated assessment.';

(62) Article 79 is deleted;

(63) the following Article 79a is inserted:

'Article 79a

Clinical investigations in combined studies

Clinical investigations that are part of combined studies, and which are subject to authorisation in accordance with Article 62, may be carried out in accordance with Article 14c of Regulation (EU) No 536/2014.

If the sponsor chooses to apply Article 14c of Regulation (EU) No 536/2014, the requirements laid down therein and in any implementing or delegated acts adopted in accordance with that Article shall apply instead of the corresponding requirements laid down in this Regulation.';

(64) Article 82 is deleted;

(65) in Article 83(4), the first sentence is replaced by the following:

'If in the course of the post-market surveillance, a need for preventive or corrective action, or both, is identified, the manufacturer shall implement the appropriate measures. The competent authorities concerned may request the manufacturer to inform them when such preventive or corrective action is taken to reduce a risk that may compromise the safety or performance of the device.';

(66) in Article 84, the second sentence is deleted;

(67) Article 86 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, the first sentence is replaced by the following:

'Manufacturers of class IIa, class IIb and class III devices, other than custom-made devices, shall prepare a periodic safety update report ('PSUR') for each device, or where relevant for each category or group of devices, summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84, together with a description of any preventive and corrective actions taken, including their rationale.';

(ii) the second and third subparagraphs are replaced by the following:

'Manufacturers of class IIb and class III devices shall update the PSUR in the first year after the certificate is issued and every two years thereafter or when there is a significant change in the benefit-risk determination or in the acceptability of undesirable side-effects. The PSUR shall be part of the technical documentation as specified in Annex III.

Manufacturers of class IIa devices shall update the PSUR when necessary. The PSURs shall be part of the technical documentation specified in Annex III. ‘;

(iii) the fourth subparagraph is deleted.

(b) paragraph 2 is replaced by the following:

‘2. For class III devices or class IIb implantable devices, other than well-established technology devices, the notified body shall review the PSUR during the surveillance assessment. The manufacturer and the notified body shall make such PSURs and the evaluation by the notified body available to competent authorities through the electronic system referred to in Article 92.’;

(68) Article 87 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, point (a) is replaced by the following

‘(a) any serious incident involving devices made available on the Union market, except expected undesirable side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;’:

(ii) the second subparagraph is replaced by the following:

‘The reports referred to in the first subparagraph shall be submitted without undue delay through the electronic system referred to in Article 92.’;

(b) paragraph 3 is replaced by the following:

‘3. Manufacturers shall report any serious incident as referred to in paragraph 1, first subparagraph, point (a), immediately after they have established that there is a causal relationship between that incident and their device or that such causal relationship is reasonably possible and not later than 30 days after they become aware of the incident.’;

(69) the following Article 87a is inserted:

‘Article 87a

Reporting of actively exploited vulnerabilities and severe incidents related to devices

1. Without prejudice to the reporting obligations regarding serious incidents and field safety corrective actions set out in Article 87, the manufacturer of a device shall report to the computer security incident response teams (‘CSIRTs’), designated as coordinators of the Member States where a device has been made available, and to the European Union Agency for Cybersecurity (ENISA), either of the following:

(a) any actively exploited vulnerability as defined in Article 3, point (42), of Regulation (EU) 2024/2847 of the European Parliament and of the Council******* contained in the device;

(b) any severe incident as referred in Article 14(5) of Regulation (EU) 2024/2847 having an impact on the security of the device.

2. The manufacturer shall submit the report referred to in paragraph 1 through the electronic system referred to in Article 92 not later than 30 days after it becomes aware of the actively exploited vulnerability or the severe incident.

3. The report referred to in paragraph 1, as well as any report submitted by a manufacturer in accordance with Article 87 that also qualifies as actively exploited vulnerability or severe incident, shall be made available simultaneously to the CSIRTs designated as coordinators of the Member States in which the device has been made available and to ENISA.

4. For the purposes of this Article, the CSIRTs designated as coordinators and ENISA shall have access to Eudamed.'

******* Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L, 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).';

(70) in Article 88(1), the first sentence is replaced by the following:

'Manufacturers shall report, by means of the electronic system referred to in Article 92, any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 8 of Annex I.';

(71) Article 89 is amended as follows:

(a) in paragraph 1, the second subparagraph is replaced by the following:

'The manufacturer shall cooperate with the competent authorities during the investigations referred to in the first subparagraph and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.';

(b) paragraph 2 is replaced by the following:

'2. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory, or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 87 is evaluated centrally at national level by their competent authority, if possible together with the manufacturer.';

(c) the following paragraph 3a is inserted:

'3a. The competent authority may request the notified body that issued a certificate for the device in question in accordance with Article 56 to provide assistance in evaluating a corrective action related to a serious incident or a field safety corrective action.';

(d) paragraph 6 is replaced by the following:

‘6. In the case of devices referred to in Article 1(8), first subparagraph, and where the serious incident or field safety corrective action is confirmed by the manufacturer to be related to a substance which, if used separately, would be considered to be a medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 9 shall inform the national competent authority or the EMA, which issued the scientific opinion on that substance in accordance with Article 52(9), of that serious incident or field safety corrective action.

In the case of devices falling within the scope of this Regulation in accordance with Article 1(6), point (g), or in accordance with Article 1(10), the competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall inform the competent authority for substances of human origin that was consulted by the notified body in accordance with Article 52(10), provided that the serious incident or field safety corrective action is confirmed by the manufacturer to be related to the derivatives of substances of human origin utilised for the manufacture of the device or to the non-viable substances of human origin or their derivatives that have an action ancillary to that of the device.’;

(e) paragraph 7 is replaced by the following:

‘7. If, after carrying out the evaluation in accordance with paragraph 3 of this Article, the evaluating competent authority identifies the need for additional corrective actions from the manufacturer to minimise the risk of recurrence of the serious incident, it shall, through the electronic system referred to in Article 92, inform, without delay, the other competent authorities of the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying events and the outcome of its assessment.’;

(f) in paragraph 9, the introductory wording is replaced by the following:

‘The competent authorities shall actively participate in a procedure in order to coordinate their assessments referred to in paragraph 3 whenever such coordination is needed to ensure a high level of protection of the health and safety of patients, users and other persons or the protection of public health throughout the Union, and in particular in the following cases:’;

(72) in Article 91, the first subparagraph is amended as follows:

(a) the introductory wording is replaced by the following:

‘The Commission may, by means of implementing acts, and after consultating the MDCG, adopt the detailed arrangements and procedural aspects necessary for the implementation of Articles 84 to 90 and Article 92 as regards the following:’;

(b) point (b) is replaced by the following:

‘(b) the reporting of serious incidents and field safety corrective actions and field safety notices, and the provision and content of the post-market surveillance plan, periodic summary reports, post-market surveillance reports, PSURs and trend reports by manufacturers as referred to in Articles 84, 85, 86, 87, 88 and 89 respectively;’;

(73) in Article 92(2), the reference to ‘Article 53’ is replaced by ‘Article 56’;

(74) Article 93 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices and on the compliance of economic operators with the obligations set out in this Regulation including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.’;

(b) the following paragraph 1a is inserted:

‘1a. Member States shall ensure that their national competent authorities are provided with adequate and sufficient technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation.’;

(c) paragraph 2 is replaced by the following:

‘2. The competent authorities shall draw up annual surveillance activity plans, taking into account the European market surveillance programme, which shall be developed and maintained by the MDCG, and local circumstances.’;

(d) the following paragraph 12 is added:

‘12. In respect of devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, the competent authorities shall cooperate with market surveillance authorities of their Member State designated in accordance with Article 70 of Regulation (EU) 2024/1689.’;

(75) Article 94 is replaced by the following:

‘Article 94

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

The competent authorities of a Member State shall, alone or in cooperation with the competent authorities of other Member States, carry out an evaluation of a device of of an economic operator covering all the relevant requirements laid down in this Regulation relating to the risk presented by the device, or to any other non-compliance of the device or of the economic operator, where they, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe either of the following:

(a) the device may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(b) the device or the economic operator concerned otherwise does not comply with the requirements laid down in this Regulation.

The relevant economic operators and, where applicable and requested, the notified body that issued a certificate for the device in question shall cooperate with the competent authorities.

The competent authorities of the Member States may request any economic operator or notified body to submit documentation available to them, where access to such documentation is needed in the interest of public health or patient safety or health.';

(76) Article 95 is amended as follows:

(a) paragraph 3 is replaced by the following:

'3. The economic operators as referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken, within the period referred to in paragraph 1, throughout the Union in respect of all the devices concerned that they have made available on the market.';

(b) paragraph 7 is amended as follows:

(i) the first subparagraph is replaced by the following:

'Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of the notified measures taken by a Member State, those measures shall be deemed to be justified.';

(ii) in the second subparagraph, the following sentence is added:

'Paragraph 4 shall not apply to such measures adopted by the Member States.';

(77) Article 96 is amended as follows:

(a) in paragraph 1, the third sentence is deleted;

(b) in paragraph 2, the second sentence of the first subparagraph is replaced by the following:

'If the Commission considers that the national measure is unjustified, the Member State concerned, as well as any Member State that has taken corresponding restrictive or prohibitive measures, shall withdraw the measure.';

(78) Article 97 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device or an economic operator does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.';

(b) in paragraph 2, the first sentence is replaced by the following:

'Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1, the Member State concerned

shall, without delay, take all appropriate measures to restrict or prohibit the product being made available on the national market or to ensure that it is recalled or withdrawn from the national market.';

(c) the following paragraph 2a is inserted:

'2a. The economic operator shall take any appropriate corrective action pursuant to paragraph 1 or 2 throughout the Union in respect of all the devices concerned that they have made available on the market, unless a competent authority takes other appropriate measures.';

(79) in Article 98(3), the fourth sentence is deleted;

(80) the title of Chapter VIII is replaced by the following:

'COOPERATION BETWEEN MEMBER STATES, THE MDCG, EXPERT LABORATORIES, EXPERT PANELS AND DEVICE REGISTERS, CONFLICTS OF INTEREST AND INTERNATIONAL COOPERATION';

(81) after the title of Chapter VIII, the following title is inserted:

'**SECTION 1**

Cooperation between Member States, the MDCG, expert panels, expert laboratories and device registers and conflict of interests';

(82) Article 101 is replaced by the following:

'Article 101

Competent authorities

The Member States shall designate the competent authority or authorities responsible for the implementation and practical application of this Regulation. They shall ensure that those authorities are entrusted with sufficient powers, resources, equipment and knowledge to effectively and efficiently perform their tasks pursuant to this Regulation. The Member States shall communicate the names and contact details of the competent authorities to the Commission which shall publish a list of competent authorities.';

(83) in Article 102, paragraph 2 is deleted;

(84) Article 103 is amended as follows:

(a) in paragraph 2, second subparagraph, the second sentence is replaced by the following:

'They shall represent the competent authorities of the Member States and the authorities responsible for notified bodies of the Member States, as applicable.';

(b) paragraph 7 is replaced by the following:

'7. The MDCG shall establish a sub-group with members representing the authorities responsible for notified bodies and may establish other standing or temporary sub-groups. Where appropriate, representatives of the coordination group referred to in Article 49 and organisations representing the interests of the medical device industry, in particular of micro, small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC, healthcare professionals, laboratories,

patients and consumers at Union level shall be invited to the MDCG and its sub-groups in the capacity of observers.';

(c) paragraph 9 is replaced by the following:

'9. The MDCG shall have the tasks laid down in Article 105 of this Regulation.';

(85) in Article 104, the second sentence is deleted;

(86) Articles 105 and 106 are replaced by the following:

'Article 105

Tasks of the MDCG

In addition to the tasks assigned to it in other provisions of this Regulation and Regulation (EU) 2017/746, the MDCG shall in particular assist the Commission in the assessment of any issue related to the implementation of those Regulations and contribute to the development of guidance aimed at ensuring their effective and harmonised implementation.

Article 106

Expert panels

1. The Commission shall, by means of implementing acts and following consultation with the MDCG, make provision for expert panels to be designated to provide scientific, clinical, technical or regulatory opinions and advice in relation to the implementation of this Regulation and of Regulation (EU) 2017/746 to the Commission, the MDCG, Member States, notified bodies or manufacturers.

   Expert panels may be designated on a standing or temporary basis.

2. Expert panels shall consist of experts with proven up-to-date clinical, scientific, technical or regulatory expertise in the field of medical devices or *in vitro* diagnostic medical devices reflecting the diversity of scientific and clinical approaches in the Union.

   Experts shall be appointed following publication of a call for expressions of interest. Depending on the type of task and the need for specific expertise, experts may be appointed to the panels for a maximum period of three years and their appointment may be renewed.

   When expert panels are requested to provide an opinion on the regulatory status of a product which involves aspects concerning the borderline with other types of products, experts with expertise in the field of the relevant other products shall be involved.

3. The experts shall observe the principles of highest scientific competence and perform their tasks with impartiality, objectivity and transparency. They shall neither seek nor take instructions from notified bodies or manufacturers. Each expert shall draw up a declaration of interests, which shall be made publicly available.

4. Expert panels shall take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals' associations.

5. Experts may be included on a list of available experts who, whilst not being formally appointed to a panel, are available to provide advice and to support the work of the expert panels as needed.

6. Experts from notified bodies shall not be involved in the clinical evaluation consultation procedure provided for in Article 54(1).

7. In addition to the tasks assigned to them in other provisions of this Regulation and of Regulation (EU) 2017/746, the expert panels may have the following tasks:

   (a) to provide scientific, clinical, technical and regulatory advice to the Commission, the MDCG, Member States or notified bodies in relation to the implementation of this Regulation or Regulation (EU) 2017/746;

   (b) to contribute to the development and maintenance of appropriate guidance and CS supporting the implementation of this Regulation or Regulation (EU) 2017/746;

   (c) to contribute to the development of standards at Union or international level, ensuring that such standards reflect the state of the art;

   (d) to contribute to the identification of concerns and emerging issues concerning the safety and performance of medical devices, including *in vitro* diagnostic medical devices.

8. When adopting their opinions or advice, the members of the expert panels shall use their best endeavours to reach consensus. If consensus cannot be reached, the expert panels shall decide by a majority of their members, and the opinion or advice shall mention the divergent positions and the grounds on which they are based.

9. The Commission shall require manufacturers and notified bodies to pay fees for opinions and advice provided by expert panels. The structure and the level of the fees, as well as the scale and type of recoverable costs, shall be established by the Commission by means of implementing acts, taking into account the objectives of the adequate implementation of this Regulation, protection of health and safety, support of innovation and cost-effectiveness and the necessity to achieve active participation in the expert panels. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

   The fees referred to in the first subparagraph shall be established in a transparent manner and on the basis of the costs for the services provided. The fees shall be reduced for manufacturers which are micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC, including in the case of a clinical evaluation consultation procedure initiated in accordance with Section 5.1, point (c), of Annex IX involving a manufacturer who is a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC. The fees related to the opinions and advice provided by expert panels are payable to EMA pursuant to Article 30, point (f), of Regulation (EU) 2022/123.

10. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend paragraph 7 of this Article by adding, adapting or removing tasks from the list of tasks of the expert panels.';

(87) the following Articles 106a and 106b are inserted:

'Article 106a

Expert laboratories

1. The Commission may, by means of implementing acts and following consultation with the MDCG, designate expert laboratories, on the basis of their expertise in the field of testing of medical devices, such as physico-chemical characterisation, microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing of specific devices, categories or groups of devices.

   The Commission shall only designate expert laboratories for which a Member State or the Joint Research Centre has submitted an application for designation.

2. Expert laboratories shall satisfy the following criteria:

   (a) have adequate and appropriately qualified staff with adequate knowledge and experience in the field of the devices for which they are designated;

   (b) have at their disposal the necessary equipment to carry out the tasks assigned to them;

   (c) have the necessary knowledge of international standards and best practices;

   (d) have an appropriate administrative organisation and structure;

   (e) ensure that their staff observe the confidentiality of information and data obtained in carrying out their tasks;

   (f) act in the public interest and in an independent manner.

3. Expert laboratories may have the following tasks:

   (a) to provide scientific and technical assistance to the Commission, the MDCG, the EMA, Member States and notified bodies in relation to the implementation of this Regulation;

   (b) to contribute to the development and maintenance of appropriate guidance and CS supporting the implementation of this Regulation;

   (c) to contribute to the development of standards at Union or international level, ensuring that such standards reflect the state of the art;

   (d) to contribute to identification of concerns and emerging issues on the safety and performance of medical devices;

   (e) to provide scientific and technical assistance to Member States and the Commission in vigilance and market surveillance activities.

4. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend paragraph 3 of this Article by adding, adapting or removing tasks from the list of tasks of the expert laboratories.

5. The expert laboratories may charge fees in accordance with predetermined and transparent terms and conditions for scientific and technical assistance provided to the EMA, Member States or notified bodies for carrying out the requested task. For the provision of services within the public interest on request of the Commission or the MDCG, the expert laboratories may be granted a Union financial contribution.

Article 106b

Support by the EMA

1. The EMA shall, on behalf of the Commission, provide scientific, technical and administrative support to the national competent authorities designated under this Regulation and under Regulation (EU) 2017/746 to facilitate the exchange of experience, cooperation and coordination with a view to ensuring a uniform application of such Regulations, in particular in the following areas:

   (a) regulatory status of products and classification of devices in accordance with Articles 4, 4a, 51, 51a and 51b of this Regulation and Articles 3, 3a, 47, 47a and 47b of Regulation (EU) 2017/746;

   (b) derogations from the applicable conformity assessment procedures in accordance with Articles 59 and 59a of this Regulation and Articles 54 and 54a of Regulation (EU) 2017/746;

   (c) clinical evaluation, clinical investigations, performance evaluation and performance studies in accordance with Chapter VI of this Regulation and Chapter VI of Regulation (EU) 2017/746, including support to the coordinating Member State for the coordinated assessment procedure for clinical investigations and performance studies referred to in Article 78 of this Regulation and Article 74 of Regulation (EU) 2017/746;

   (d) vigilance and market surveillance in accordance with Chapter VII of this Regulation and Chapter VII of Regulation (EU) 2017/746, including support to the coordinating competent authority for the coordinated procedure referred to in Article 89(9) of this Regulation and Article 84(9) of Regulation (EU) 2017/746.

2. The EMA shall provide scientific, technical and administrative support to the Commission for the establishment of Union regulatory sandboxes in accordance with Article 59c of this Regulation and Article 54c of Regulation (EU) 2017/746.

3. The EMA shall set up a support scheme for manufacturers of medical devices and *in vitro* diagnostic medical devices, which are micro, small and medium-sized within the meaning of Recommendation 2003/361/EC, regarding the requirements of this Regulation and of Regulation (EU) 2017/746.

4. The EMA shall have access to Eudamed and any electronic system referred to in Article 33(2) of Regulation (EU) 2017/745 or in Article 30(2) of Regulation (EU) 2017/746 that is not included in Eudamed.';

(88) in Article 107(1), the fourth and fifth sentences are replaced by the following:

‘The declaration of interests shall be made publicly available. This Article shall not apply to the representatives of stakeholder organisations participating in the MDCG or its sub-groups.’;

(89) in Article 108, the first sentence is replaced by the following:

‘The Commission, the Member States and the EMA shall take all appropriate measures to encourage the establishment of registers and databanks for specific types of devices, where appropriate including *in vitro* diagnostic medical devices, setting common principles to collect comparable information.’;

(90) the following Section 2 is inserted after Article 108:

‘***SECTION 2 – International cooperation***

Article 108a

International regulatory and administrative cooperation

1. The Commission shall pursue international regulatory cooperation in the field of medical devices and *in vitro* diagnostic medical devices with a view to promoting a high level of protection of public health and patient safety, fostering innovation and enhancing efficiency of regulatory compliance through global convergence. For that purpose, the Commission and the Member States shall contribute to the development and adoption of global principles, standards, and guidance which provide a high level of international convergence in the field of medical devices and *in vitro* diagnostic medical devices, including in relation to safety, performance, quality management systems, conformity assessment, and post-market surveillance.

2. The Commission shall participate in relevant international fora in the field of medical devices and *in vitro* diagnostic medical devices, including the International Medical Device Regulators Forum (IMDRF), the Medical Device Single Audit Programme (MDSAP) and International Standardisation Organisations.

3. In its activities in accordance with paragraphs 1 and 2, the Commission shall be supported by experts nominated by the Member States in view of their competence in medical devices or *in vitro* diagnostic medical devices.

4. The Commission may sign administrative arrangements with authorities of third countries and with international organisations for the purpose of regulatory cooperation in the field of medical devices and *in vitro* diagnostic medical devices, including:

   (a) exchange of information and best practices;

   (b) joint or coordinated inspections and assessments;

   (c) coordinated actions relating to safety issues, including recalls or safety communications.

   Where the Commission signs such administrative arrangements which include the exchange of information or data, the administrative arrangement shall provide for protection of such information or data in accordance with Article 109 of this Regulation or in Article 102 of Regulation (EU) 2017/746, as applicable.

5. The Union shall finance the activities of the Commission and the Member States relating to international cooperation as referred to in this Article and the reliance mechanisms referred to in Article 108b.

Article 108b

Reliance mechanisms

1. The Commission, may participate in bilateral or multilateral reliance mechanisms or reliance programmes in the field of medical devices and *in vitro* diagnostic medical devices, which shall enable the use of assessments, inspections, and other regulatory decisions carried out or taken by regulatory authorities of third countries or international organisations or international bodies, provided that the following conditions are fulfilled:

   (a) the reliance mechanism or reliance programme ensures a level of health and safety protection equivalent to that required under this Regulation or Regulation (EU) 2017/746, as applicable;

   (b) effective arrangements for mutual exchange of information, transparency, and oversight are in place, providing for the confidentiality of information and data referred to in Article 109 of this Regulation or Article 102 of Regulation (EU) 2017/746, as applicable.

2. The Commission may invite Member States to nominate experts, in view of their competence in medical devices or *in vitro* diagnostic medical devices, who participate in reliance mechanisms or reliance programmes referred to in paragraph 1.

3. Reliance mechanisms or reliance programmes referred to in paragraph 1 shall be taken into consideration by competent authorities, economic operators or notified bodies in the framework of the implementation of this Regulation or of Regulation (EU) 2017/746, as applicable.

4. The Commission may adopt implementing acts establishing detailed rules for the recognition of reliance mechanisms or reliance programmes, which may include conditions for participation of notified bodies to reliance mechanisms or reliance programmes, requirements relating to the scope of assessments, inspections or other regulatory decisions carried out or taken in the course of reliance mechanisms or reliance programmes, and procedural safeguards for manufacturers. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 108c

Capacity building and technical assistance

1. The Commission may support the strengthening of regulatory capacity in third countries, including through the provision of technical assistance, training, exchange of experts, and dissemination of best practices.

2. The Commission may invite Member States to nominate experts, in view of their competence in medical devices or *in vitro* diagnostic medical devices, to participate in its activities referred to in paragraph 1.

3. The activities referred to in paragraph 1 may be financed through relevant Union programmes or external action instruments.';

(91) the following Article 110a is added:

'Article 110a

Submission of information or documents

The submission of information or documents in accordance with this Regulation shall take place electronically.';

(92) in Article 111, paragraph 1 is replaced by the following:

'1. This Regulation shall be without prejudice to the possibility for Member States and the Commission to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost-recovery principles.';

(93) Article 112 is deleted;

(94) Article 116 is deleted;

(95) in Article 120, the following paragraphs 14 and 15 are added:

'14. By way of derogation from Article 5 and from paragraphs 3 to 3e of this Article, a device as referred to in paragraph 3a or 3b of this Article that meets the criteria for an orphan device as referred to in Article 52a(3) may be placed on the market or put into service after the dates referred to in paragraphs 3a and 3b of this Article if the following conditions are met:

(a) an expert panel referred to in Article 106 has issued an opinion confirming the fulfilment of the criteria for an orphan device as referred to in Article 52a(3);

(b) there are no significant changes in the design and intended purpose of the device;

(c) the device does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

The requirements of this Regulation, with the exception of Chapters IV, V and VI, shall apply to a device referred to in the first subparagraph.

By way of derogation from Article 86(1), manufacturers of class IIa devices, class IIb devices and class III devices placed on the market or put into service in accordance with this paragraph shall update the PSUR at least annually. On an annual basis, the manufacturer shall submit the PSUR and, where applicable, an update of the summary of safety and clinical performance to the competent authority of the Member State in which it is established.

The competent authority of the Member State may require the manufacturer to conduct defined post-market surveillance or PMCF activities within a specified period of time to generate additional clinical data to confirm the safety and performance of the device and to evaluate any undesirable side-effects and the acceptability of the benefit-risk ratio.

Devices placed on the market or put into service in accordance with this paragraph, which do not have a valid certificate in accordance with paragraph 2, shall not bear the CE marking. In its EU declaration of conformity, the manufacturer shall make reference to the fact that the device is an orphan device placed on the market or put into service in accordance with this provision.

The manufacturer shall inform the intended users about the fact that the device is an orphan device placed on the market or put into service in accordance with this provision, where applicable, in the summary of safety and clinical performance and in the instructions for use or any other accompanying documentation.

At least every 10 years, the manufacturer shall request an opinion from an expert panel referred to in Article 106 confirming the fulfilment of the criteria for an orphan device as referred to in Article 52a(3).

15. As regards devices for which a conformity assessment procedure is pending on …[*OP please insert the date = six months after the date of entry into force of this Regulation*], or for which a certificate is issued by a notified body before that date, the manufacturer and the notified body may agree to continue applying the provisions of this Regulation in the form applicable before …[*OP please insert the date = six months after the date of entry into force of this Regulation*] until the conformity assessment procedure is finalised or until the certificate is renewed.';

(96) Article 121 is replaced by the following:

'Article 121

Evaluation

No sooner than …[*Publications Office, please insert the date five years after the date of application of this Regulation*], the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council.

Member States and notified bodies shall provide the Commission with the information necessary for the preparation of that report.'

(97) in Article 123(3), point (d), the following third subparagraph is added:

'After the date of application of the provisions referred to in the first subparagraph of this point, where Member States maintain national databases, the relevant information available in Eudamed for those national databases shall be retrieved from Eudamed.';

(98) Annexes I, II, III, VI, VII, VIII, IX, X, XI, XII, XIII, XIV and XV are amended in accordance with Annex I to this Regulation.

Article 2

Amendments to Regulation (EU) 2017/746

Regulation (EU) 2017/746 is amended as follows:

(1) Article 1(4) is replaced by the following:

‘4. Any device which, when placed on the market or put into service, incorporates, as an integral part, a medical device as defined in Article 2, point (1), of Regulation (EU) 2017/745 that has an action ancillary to that of the *in vitro* diagnostic medical device, the integral product shall be governed by this Regulation. In that case, the relevant general safety and performance requirements set out in Annex I to Regulation (EU) 2017/745 shall apply as far as the safety and performance of the medical device part are concerned.

However, if the action of the medical device is principal and not ancillary to that of the *in vitro* diagnostic medical device, the integral product shall be governed by Regulation (EU) 2017/745. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the *in vitro* diagnostic medical device part are concerned.’;

(2) Article 2 is amended as follows:

(a) in point (2), first subparagraph, point (f) is replaced by the following:

‘(f) to define or monitor therapeutic measures.’;

(b) in point (7), the introductory wording is replaced by the following:

‘‘companion diagnostic’ means a device which is essential for the safe and effective use of one or more corresponding medicinal product(s) to:’;

(c) point (8) is replaced by the following:

‘(8) ‘generic device group’ means a set of devices having the same or similar intended purposes and a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;’;

(d) the following points (75), (76), (77) and (78) are added:

‘(75) ‘combined study’ means a clinical trial as defined in Article 2(2), point (2), of Regulation (EU) No 536/2014, combined with a performance study, and/or a clinical investigation as defined in Article 2, point (45), of Regulation (EU) 2017/745;

(76) ‘regulatory sandbox’ means a controlled environment set up by a competent authority which offers manufacturers or prospective manufacturers the possibility to develop, test, validate and use, where appropriate in real-world conditions, an innovative product or technology potentially falling within the scope of this Regulation, pursuant to a sandbox plan for a limited time under regulatory supervision’;

(77) ‘sandbox plan’ means a document agreed between the participating manufacturer(s) or prospective manufacturer(s) and the competent authority describing the objectives, conditions, timeframe, methodology and requirements for the activities carried out within the regulatory sandbox;

(78) ‘Union regulatory sandbox’ means a controlled envrironment set up by the Commission for testing alternative or new regulatory requirements or enforcement practices and appraising their validity in comparison with existing requirements and practices under this Regulation for a limited time.’;

(3) Article 3 is replaced by the following

'Article 3

Regulatory status of products

1. The competent authorities of the Member States shall coordinate their activities when determining whether a specific product, or category or group of products, falls within the definition of an '*in vitro* diagnostic medical device' or of an 'accessory for an *in vitro* diagnostic medical device'.

2. The Member States shall ensure an appropriate level of consultation of the relevant competent authorities of the Member States in the fields of medical devices, medicinal products, substances of human origin (SoHO), biocides, food, cosmetics or other products subject to Union legislation, where the determination of the regulatory status of a product involves aspects concerning the borderline with any of those types of products. In that case, Member States shall also ensure an appropriate level of consultation of the relevant advisory or regulatory bodies established in the relevant Union legislation, such as the European Medicines Agency (EMA), the SoHO Coordination Board, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA).

3. Where a competent authority of a Member State, after having performed an evaluation in accordance with Article 89, considers that a product that is CE marked in accordance with Article 18, does not fall within the scope of this Regulation, it shall consult the competent authorities of the other Member States regarding its envisaged measure determining the regulatory status of the product in question.

4. Where a competent authority of a Member State raises a substantiated disagreement regarding the envisaged measure referred to in paragraph 3, the consulting authority shall refer the matter to an expert panel as referred to in Article 106 of Regulation (EU) 2017/745 and shall give utmost consideration to the opinion of that expert panel.

5. The results of the coordination activities of the competent authorities in accordance with this Article and the opinions of the expert panel delivered in accordance with paragraph 4 of this Article and Article 3a(2) shall be made publicly available, without disclosing any confidential information as referred to in Article 102.

6. The Commission may, by means of implementing acts, lay down the procedure, including timelines, for the application of paragraphs 1 to 4 of this Article and of Article 3a. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).';

(4) the following Article 3a is inserted:

'Article 3a

Opinion on and determination of the regulatory status of products at Union level

1. A competent authority, a notified body, a manufacturer, a developer of a product or the Commission may submit a substantiated request for an opinion from an expert panel referred to in Article 106 of Regulation (EU) 2017/745 on

the question whether a specific product, or category or group of products, falls within the definitions of '*in vitro* diagnostic medical device' or 'accessory for an *in vitro* diagnostic medical device'. Where, in such a request, the requester considers that the product in question is an *in vitro* diagnostic medical device, the request shall also specify the proposed classification of the device in accordance with Article 47 and Annex VIII.

2. The expert panel shall provide its opinion without undue delay. The requester shall give utmost consideration to the opinion of the expert panel.

3. Having regard to the expert panel opinion referred to in paragraph 2 or in Article 3(4), a Member State may submit a substantiated request to the Commission to determine whether a specific product, or category or group of products, falls within the definition of '*in vitro* diagnostic medical device' or of 'accessory for an *in vitro* diagnostic medical device'.

The Commission shall decide on the substantiated request of the Member State, or on its own initiative, by means of implementing acts, which shall be adopted in accordance with the examination procedure referred to in Article 107(3).

The Commission may ask the expert panel for clarifications or refer the opinion back to the expert panel for further consideration, including in cases where a Member State's substantiated request raises new questions of a scientific or technical nature.

4. This Article shall not apply where within the framework of another Union legislation the regulatory status of the product, or category or group of products concerned has been determined as falling within the scope of that other Union legislation, or where a procedure for the determination of the regulatory status is ongoing within the framework of another Union legislation.';

(5) Article 5 is amended as follows:

(a) paragraph 5 is amended as follows:

(i) the first subparagraph is amended as follows:

(1) point (a) is replaced by the following:

'(a) the devices are not transferred to another legal entity, except to another health institution in the duly justified interest of public health, patient safety or patient health, or to prepare or respond to a public health emergency;';

(2) point (c) is replaced by the following:

'(c) the laboratory of the health institution is compliant with standard EN ISO 15189 or, where applicable, national provisions for quality and competence in medical laboratories, including national provisions regarding accreditation;';

(3) point (d) is deleted;

(4) point (e) is replaced by the following:

'(e) upon request by a competent authority, the health institution provides information on the use of such devices to its

competent authority, which shall include the justification referred to in point (a);';

(5) point (f)(iii) is replaced by the following:

'(iii) a declaration either that the health institution is accredited to the standard referred to in point (c) or that the devices meet the relevant general safety and performance requirements set out in Annex I and, where applicable, information on which requirements are not fully met with a reasoned justification therefor;';

(6) point (g) is replaced by the following:

'(g) as regards class D devices in accordance with the rules set out in Annex VIII, where the health institution is not accredited to the standard referred to in point (c), the health institution draws up documentation sufficiently detailed to enable the competent authority to ascertain that the relevant general safety and performance requirements set out in Annex I are met;';

(7) point (h) is deleted;

(ii) in the second subparagraph, the first sentence is deleted;

(iii) the following subparagraphs are added:

'For the purposes of the first subparagraph, point (a), in the case of a transfer of the device to another health institution, the transferring and receiving health institutions shall ensure traceability of the device.

For the purposes of the first subparagraph, point (i), where the device is transferred in accordance with the first subparagraph, point (a), the receiving health institution shall report any incident related to the device to the transferring health institution.

This paragraph shall also apply to devices manufactured and used within a laboratory that is established in the Union and provides consistent, state of the art testing services for clinical research, provided those devices are intended exclusively for use in the framework of a clinical trial subject to Regulation (EU) No 536/2014 of the European Parliament and of the Council*. Where, in this paragraph, reference is made to a health institution, such reference shall also be understood as reference to a laboratory referred to in the first sentence of this subparagraph.

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*Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1, ELI: http://data.europa.eu/eli/reg/2014/536/oj).';

(b) the following paragraph 7 is added:

'7. The Commission is empowered to adopt delegated acts in accordance with Article 108, to amend the general safety and performance requirements set out in Annex I in order to adapt them to scientific or

technical progress or to international developments, or to add requirements in relation to emerging risks or technologies.

8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council**, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation.

** Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).';

(6) Article 6 is amended as follows:

(a) the following paragraph 2a is inserted:

'2a. Any natural or legal person offering a device in accordance with paragraph 1 or a service in accordance with paragraph 2 shall provide in the offer at least the information referred to in Section 20.2., points (a) to (e) and (m), of Annex I and access to the instructions for use.';

(b) paragraphs 3 and 4 are replaced by the following:

'3. Upon request by a competent authority, any natural or legal person offering a device in accordance with paragraph 1 or a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity drawn up in accordance with Article 17 for the device concerned and cooperate with the competent authorities of the Member State in which the device or the service is offered.

4. A Member State may, on grounds of protection of public health, require a provider of a service, as defined Article 1(1), point (b), of Directive (EU) 2015/1535, or the provider of the service referred to in paragraph 2, to cease its activity.';

(7) in Article 7, the following subparagraph is added:

'Without prejudice to national law regarding the exercise of the medical profession, the first subparagraph shall also apply to devices used for the provision of a service referred to in Article 6(2).';

(8) in Article 9(1), the first sentence is replaced by the following:

'Where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG, may, by means of implementing acts, adopt common specifications (CS) in respect of the requirements set out in this Regulation, in particular the reports and plans to be drawn up by manufacturers, the

general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III, the conformity assessment procedures set out in Annexes IX, X and XI, the performance evaluation and PMPF set out in Annex XIII or the requirements regarding performance studies set out in Annexes XIII and XIV.';

(9) Article 10 is amended as follows:

(a) paragraphs 3 and 6 are deleted;

(b) paragraph 8 is amended as follows:

(i) in the first subparagraph, the first sentence is replaced by the following:

'Manufacturers shall put in place an appropriate quality management system to ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation.';

(ii) the third subparagraph is deleted;

(c) paragraph 9 is deleted;

(d) paragraph 10 is amended as follows:

(i) in the first subparagraph, the following sentence is added:

'When determining the official language of the Union in which the information set out in Section 20 of Annex I or other information to be provided by the manufacturer shall be made available, Member States shall consider accepting another official language of the Union in which the information is made available, taking into consideration the technical knowledge, experience, education or training of the average intended user(s).';

(ii) the second subparagraph is deleted;

(e) paragraph 12 is deleted;

(f) in paragraph 13, the third and fourth subparagraphs are deleted;

(g) paragraph 14 is replaced by the following:

'14. Where manufacturers have their devices designed and manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 26(3). In those cases, the manufacturer shall ensure that the relevant parts of the technical documentation are drawn up, kept up to date and, upon request, made available to the competent authorities in accordance with paragraphs 4 and 7 by the legal or natural person that has designed and manufactured the device. In addition, the manufacturer shall draw up, keep up to date and, upon request, make available to the competent authorities the remaining parts of the technical documentation, in particular those referred to in Section 2 of Annex II and in Annex III.';

(h) paragraph 15 is deleted;

(10) Article 10a is amended as follows:

(a) in paragraph 1, second subparagraph, the first sentence is replaced by the following:

‘The information referred to in the first subparagraph shall be provided at least six months before the anticipated interruption or discontinuation or, if this is not possible, without undue delay after the manufacturer becomes aware of the anticipated interruption or discontinuation.’;

(b) the following paragraphs 4, 5 and 6 are added:

‘4. The Commission, where necessary in cooperation with the EMA, shall set up, maintain, and manage an IT system to facilitate the reporting and information exchange regarding cases of interruption or discontinuation of the supply of devices in accordance with paragraphs 1, 2 and 3. That IT system shall be integrated in or interoperable with the European database on medical devices referred to in Article 30. It shall also enable health institutions and healthcare professionals to inform competent authorities about the unavailability or the immediate risk of unavailability of devices needed for the exercise of their professional activity.

5. The EMA, in collaboration with the Executive Steering Group on Shortages of Medical Devices (MDSSG) established by Article 21 of Regulation (EU) 2022/123 of the European Parliament and of the Council***, shall develop a methodology to identify the devices, or categories of devices, for which it is reasonably foreseeable that an interruption or discontinuation of supply could result in serious harm or a risk of serious harm to patients or public health as referred to in paragraph 1. Based on that methodology, the EMA, in collaboration with the MDSSG and in agreement with the Commission shall draw up, publish and keep up to date a list of devices, or categories of devices, to which paragraphs 1, 2 and 3 shall apply. For the purpose of this paragraph, the MDCG, representatives of manufacturers, other relevant actors in the supply chain for the medical device sector and representatives of healthcare professionals, of patients and of consumers may be consulted as necessary.

6. The competent authorities of the Member States or the Commission may request the manufacturers of devices included in the list drawn up in accordance with paragraph 5 to provide all necessary information regarding risks and weaknesses within the supply chain which may affect the supply of such devices, including production capacity and volume of sales.

*** Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj).’;

(11) in Article 11, paragraphs 4 and 5 are deleted;

(12) in Article 14, paragraph 2 is amended as follows:

(a) in the first subparagraph, point (d) is replaced by the following:

‘(d) that, where applicable, a UDI has been assigned by the manufacturer in accordance with Article 24(3).’;

(b) the second subparagraph is replaced by the following:

'In order to meet the requirements referred to in the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor.';

(13) Article 15 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of *in vitro* diagnostic medical devices.';

(b) paragraph 2 is replaced by the following:

'2. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC**** shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person at their disposal.

**** Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).';

(c) in paragraph 3, point (c) is replaced by the following:

'(c) the post-market surveillance obligations are complied with in accordance with Article 78;';

(d) paragraph 6 is replaced by the following:

'6. Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for *in vitro* diagnostic medical devices in the Union.';

(14) Article 16 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, the introductory wording is replaced by the following:

'A distributor, an importer or another natural or legal person who places a product on the market or puts it into service shall assume the obligations incumbent on manufacturers if it does any of the following:'

(ii) the second subparagraph is replaced by the following:

'The first subparagraph shall not apply to any healthcare professional or any other person who, while not considered a manufacturer, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.';

(b) paragraph 4 is deleted;

(15) Article 17 is amended as follows:

(a) in paragraph 1, the first sentence is replaced by the following:

‘The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled in relation to the device that is covered by that declaration.’;

(b) the following paragraph 2a is inserted:

‘2a. Declarations of conformity in accordance with paragraphs 1 and 2 may be provided in electronic form.’;

(16) The following Article 19a is inserted:

‘Article 19a

Kits

A kit may contain the following components:

(a) *in vitro* diagnostic medical devices or their accessories which may or may not individually bear the CE marking in conformity with this Regulation;

(b) medical devices or their accessories bearing the CE marking in conformity with Regulation (EU) 2017/745;

(c) other products which are used within the *in vitro* diagnostic examination or the presence of which in the kit is otherwise justified, and where those products are in conformity with the Union legislation that applies to them.’

(17) the heading of Chapter III is replaced by the following:

‘IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES’;

(18) Article 24 is amended as follows:

(a) in paragraph 1, the following point (ba) is inserted:

‘(ba) a Basic UDI-DI, as defined in Part C of Annex VI;’;

(b) paragraph 2 is amended as follows:

(i) point (d) is replaced by the following:

‘(d) the entity gives access to its system for the assignment of UDIs to all interested users in accordance with a set of predetermined and transparent terms and conditions taking into consideration the interests of micro, small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC;’;

(ii) in point (e), the following subpoint (iv) is added:

‘(iv) offers its system for the assignment of UDIs to manufacturers that are micro and small enterprises within the meaning of Recommendation 2003/361/EC under preferential conditions that take into account the specific needs of such enterprises and are proportionate to their size.’;

(c) paragraph 3 is replaced by the following:

‘3. Before placing a device, other than a device for performance study, on the market, the manufacturer shall, in accordance with the rules of the issuing entity designated by the Commission in accordance with

paragraph 2, assign to the device, a Basic UDI-DI and UDI as defined in Part C of Annex VI. If applicable, the manufacturer shall assign a UDI-DI to all higher levels of packaging.';

(d) the following paragraph 3a is inserted:

'3a. For devices that are the subject of a conformity assessment as referred to in Article 48(3) and (4), Article 48(7), second subparagraph, Article 48(8), and Article 48(9), second subparagraph, the assignment of a Basic UDI-DI referred to in paragraph 1 of this Article shall be done before the manufacturer applies to a notified body for that assessment.';

(e) in paragraph 10, points (a) and (b)are replaced by the following:

'(a) amending the list of information set out in Parts A and B of Annex VI in the light of technical progress; and

(b) amending Annex VI in the light of experience obtained from the implementation of the UDI system, or international developments and technical progress in the field of Unique Device Identification.';

(19) Article 26 is replaced by the following:

'Article 26

Registration of devices

1. Before placing a device, other than a device for performance study, on the market, the manufacturer shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device, as applicable. The manufacturer shall keep up to date the information provided to the UDI database.

2. For devices that are the subject of a conformity assessment as referred to in Article 48(3) and (4), Article 48(7), second subparagraph, Article 48(8), and Article 48(9), second subparagraph, the notified body shall confirm in Eudamed that the information referred to in Part B of Annex VI is correct.';

(20) in Article 27(2), the following sentence is added:

'Where national distributor databases require information on devices, such databases shall allow for the retrieval of the device information from the electronic systems referred to in Article 30(2), points (a) and (b).';

(21) Article 28 is amended as follows:

(a) the title is replaced by the following:

'**Registration of economic operators**';

(b) paragraphs 1 and 2 are replaced by the following:

'1. Before placing a device on the market, manufacturers, authorised representatives and importers shall, in order to register, submit to the electronic system referred to in Article 27 the information referred to in Part A of Annex VI, provided that they have not already registered in accordance with this Article. In cases where the conformity assessment procedure requires the involvement of a notified body pursuant to Article

48, the information referred to in Part A of Annex VI shall be provided to that electronic system before applying to the notified body.

2. Without undue delay, the competent authority shall verify the data entered pursuant to paragraph 1, obtain a single registration number ('SRN') from the electronic system referred to in Article 27 and issue it to the manufacturer, the authorised representative or the importer';

(c) in paragraph 4, the words 'one week' are replaced by the words 'two weeks';

(d) paragraph 6 is deleted;

(e) paragraph 7 is replaced by the following:

'7. The data entered pursuant to paragraph 1 of this Article in the electronic system referred to in Article 27 shall be accessible to the public, except for details regarding the person responsible for regulatory compliance referred to in Part A, point 1.4 of Annex VI.';

(22) Article 29 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. For companion diagnostics, class C devices for self-testing and class D devices, other than devices for performance studies, the manufacturer shall draw up a summary of safety and performance.

The summary of safety and performance shall be written in a way that is clear to the intended user.

The draft of the summary of safety and performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 48. The manufacturer shall ensure that the summary of safety and performance is available to the public in Eudamed and shall mention on the label or instructions for use where the summary is available. ';

(b) paragraph 2 is amended as follows:

(i) point (a) is replaced by the following:

'(a) the identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN, and a reference to the location of the instructions for use in Eudamed;';

(ii) points (b), (f), (g) and (h) are deleted;

(23) in Article 30(2), the following subparagraph is added:

'By way of derogation from the first subparagraph, the Commission may decide that one or more of the electronic systems referred to in that subparagraph are not to be included in Eudamed. In that case, the Commission shall ensure that the electronic system is interoperable with Eudamed.';

(24) Article 31 is replaced by the following:

'Article 31

Application of Chapter IV of Regulation (EU) 2017/745

Article 35 and Articles 37 to 50 of Regulation (EU) 2017/745 shall apply, *mutatis mutandis*, to the following:

(a) the authorities responsible for notified bodies to be appointed by Member States for the purpose of this Regulation and their exchange of experience;

(b) the conformity assessment bodies applying for designation under this Regulation and the assessment of their applications;

(c) the nomination of experts for joint assessment and the funding of activities related to the designation and monitoring of notified bodies;

(d) the designation and notification procedure regarding notified bodies under this Regulation, their subsidiaries and subcontracting, and their identification number;

(e) the language requirements;

(f) the monitoring of notified bodies;

(g) changes to the designation and notification of notified bodies and challenges to their competence;

(h) the coordination of notified bodies;

(i) the access to notified bodies and fees.';

(25) Article 32 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Notified bodies shall fulfil the tasks for which they are designated in accordance with this Regulation in the public interest. They shall satisfy the organisational and general requirements and the quality management, resource and process requirements, as set out in Annex VII, that are necessary to fulfil those tasks in an effective, independent, diligent and expeditious manner.

Notified bodies designated for conformity assessment activities relating to devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, or that use high-risk AI systems as safety components, shall also meet the requirements set out in Article 31(4), (5), (10) and (11) of that Regulation.';

(b) the following paragraph 4 is added:

'4. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend Annex VII in order to adapt to technical and scientific progress regarding conformity assessment in the field of *in vitro* diagnostic medical devices, including developments at international level.';

(26) Articles 33 to 46 are deleted;

(27) Article 47 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. The competent authorities shall coordinate their activities when determining the classification of a device, or a category or group of devices. The results of the coordination activities of the competent

authorities, including the result of any decision or measure adopted by a competent authority in accordance with Article 47a or 47b and any opinion issued by an expert panel in relation to classification shall be made publicly available, without disclosing any confidential information as referred to in Article 102.';

(b) in paragraph 3, point (b), is replaced by the following :

'(b) that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII, taking into consideration the principle of proportionality and classification of devices at international level.';

(c) paragraph 5 is replaced by the following:

'5. In order to ensure the uniform application of the rules set out in Annex VIII, and taking account of the relevant scientific opinions of the relevant scientific committees or expert panels, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.';

(d) the following paragraph 7 is added:

'7. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend Annex VIII in order to adapt it to technical or scientific progress or to take into account developments regarding classification of devices at international level.';

(28) the following Articles 47a and 47b are inserted:

'Article 47a

Classification in the event of a dispute between manufacturer and notified body

1. A manufacturer or a notified body may refer any dispute between them arising from the application of Annex VIII to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State in which the authorised representative referred to in Section 2.2., second paragraph, point (b), last indent, of Annex IX has its registered place of business.

   The competent authority of the Member State in which the manufacturer has its registered place of business shall notify the MDCG and the Commission of its decision. The decision shall be made available upon request.

2. Within 30 days of receipt of the referral referred to in paragraph 1, the competent authority shall consult the other Member States regarding its draft classification decision.

3. Where, within 30 days of receipt of the consultation referred to in the paragraph 2, no substantiated disagreement is raised by a Member State, the competent authority shall adopt its decision within 90 days of receipt of the referral referred to in paragraph 1.

4. Where, within 30 days of receipt of the consultation referred to in paragraph 2, a substantiated disagreement is raised by a Member State regarding the notified envisaged decision on the classification, the matter shall be referred to an expert panel as referred to in Article 106 of Regulation (EU) 2017/745. That expert panel shall deliver an opinion on the classification of the device within 30 days. The competent authority may ask the expert panel for clarifications on its opinion.

5. Within 30 days of receipt of the expert panel opinion, or any requested clarification, the competent authority shall adopt its decision, giving utmost consideration to the expert panel opinion. It shall notify the other Member States and the Commission of its decision without undue delay.

6. The Commission may, by means of implementing acts, lay down further details of the procedure for the application of this Article and of Article 47b. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 47b

Challenges to the classification of CE marked devices

1. Where a competent authority, after having performed an evaluation in accordance with Article 89, considers that a device that is CE marked in accordance with Article 18, is not classified in accordance with Annex VIII, it shall consult the other Member States regarding its envisaged measure on the classification of the device.

2. Where, within 30 days of receipt of the consultation referred to in paragraph 1, no substantiated disagreement is raised by a Member State, the competent authority may adopt the measure on the classification of the device in question and shall notify the other Member States and the Commission of its decision giving the reasons for the decision.

3. Where, within 30 days of receipt of the consultation referred to in paragraph 1, a substantiated disagreement is raised by a Member State regarding the notified envisaged measure on the classification, the matter shall be referred to an expert panel referred to in Article 106 of Regulation (EU) 2017/745, which shall deliver an opinion on the classification of the device within 30 days. The competent authority may ask the expert panel for clarifications on its opinion.

4. The competent authority shall give utmost consideration to the expert panel opinion. Where the competent authority adopts a measure on the classification, it shall notify the other Member States and the Commission of its measure without undue delay.';

(29) Article 48 is amended as follows:

(a) in paragraph 3, the second and third subparagraphs are deleted;

(b) in paragraph 4, the second subparagraph is deleted;

(c) paragraphs 5 and 6 are deleted;

(d) paragraph 7 is replaced by the following:

‘7. Manufacturers of class C devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX.’;

(e) in paragraph 8, the second subparagraph is deleted;

(f) paragraph 9 is replaced by the following:

‘9. Manufacturers of class B devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX.’;

(g) the following paragraph 9a is inserted:

‘9a. Manufacturers of class B devices, other than devices for performance study, may, instead of the conformity assessment procedure referred to in paragraph 9, choose to apply a conformity assessment as specified in Annex X coupled with a conformity assessment as specified in Annex XI with the exception of its Section 5.’;

(h) in paragraph 10, the second subparagraph is deleted;

(i) the following paragraphs 10a and 10b are inserted:

‘10a. In the case of devices for self-testing, in addition to the procedures applicable pursuant to paragraph 3, 7 or 9, the procedure specified in Section 5.1 of Annex IX shall also apply.

10b. In the case of companion diagnostics, in addition to the procedures applicable pursuant to paragraph 3, 4, 7 or 8, the procedure specified in Section 5.2 of Annex IX or in Section 3, point (k), of Annex X, as applicable, shall also apply.’;

(j) paragraphs 12 and 13 are replaced by the following:

‘12. The documents relating to the procedures referred to in paragraphs 1 to 4 and 7 to 10b shall be available in any official language of the Union acceptable to the notified body.

13. The Commission may, by means of implementing acts, specify the detailed arrangements and procedural aspects of the conformity assessment procedures with regard to any of the following aspects:

(a) in respect of class B and class C devices, the basis for the selection of the representative device for the assessment of the technical documentation as referred to in Section 2.3 of Annex IX;

(b) the modalities of unannounced on-site audits and sample tests to be conducted by notified bodies in accordance with Section 3.4 of Annex IX, taking into account the risk-class and the type of device;

(c) the frequency of samples of the manufactured devices or batches of class D devices to be sent to an EU reference laboratory designated pursuant to Article 100, in accordance with Section 4.12 of Annex IX and Section 5.1 of Annex XI;

(d) the physical, laboratory or other tests to be carried out by notified bodies in the context of sample tests, assessment of technical documentation and type;

(e) the modalities of the conformity assessment procedures regarding breakthrough devices and orphan devices set out in Article 48a.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 107(3).';

(k) the following paragraph 14 is added:

'14. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend Annexes IX, X and XI in order to adapt those Annexes to technical or scientific progress or to developments regarding conformity assessment of devices at international level and to take into account the needs of particular devices in view of their special characteristics.';

(30) the following Articles 48a and 48b are inserted:

'Article 48a

Conformity assessment of breakthrough devices and of orphan devices

1. For the conformity assessment of breakthrough devices and orphan devices, for which a notified body is involved in the conformity assessment, the procedures laid down in Article 48 shall apply subject to the specific arrangements set out in this Article.

2. A device shall be considered a breakthrough device if it meets the following criteria:

(a) the device is expected to introduce in the Union a high degree of novelty with respect to the device technology or the related clinical procedure or the application of the device in clinical practice;

(b) the device is expected to provide a significant positive clinical impact on patient or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following:

(i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art;

(ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.

3. A device shall be considered an orphan device if it meets the following criteria:

(a) the device is intended to provide information on a disease or condition that presents in not more than 12 000 individuals in the Union per year;

(b) at least one of the following criteria is met:

(i) there are insufficient available alternatives;

(ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art.

4. Upon a duly substantiated request by a manufacturer or a notified body, an expert panel as referred to in Article 106 of Regulation (EU) 2017/745 shall provide an opinion as to whether the criteria set out in paragraph 2 or 3 of this

Article, as applicable, are fulfilled. That opinion shall be published on a dedicated website without disclosing any confidential information as referred to in Article 102 and shall be duly taken into consideration by the manufacturer and the notified body.

5. Where the opinion of the expert panel confirms the fulfilment of the criteria set out in paragraph 2 or 3 of this Article, the manufacturer of a breakthrough device or of an orphan device, as applicable, may request advice from the expert panels referred to in Article 106 of Regulation (EU) 2017/745 regarding its performance evaluation strategy and appropriate analytical or clinical performance data for the performance evaluation of the device.

6. For a confirmed breakthrough device or an orphan device, as applicable, the notified body involved in the conformity assessment procedure set out in Article 48 shall prioritise the conformity assessment and apply, where appropriate, a rolling review with a view to reduce assessment timelines.

   The notified body shall give due consideration to an opinion or advice provided by the expert panel in accordance with paragraph 4 or 5 and, where it does not follow such opinion or advice, it shall provide duly justified reasons. The notified body may ask the expert panel to clarify the opinion it has provided.

7. The notified body shall issue a certificate pursuant to Article 51 where the pre-market clinical evidence, even if based on limited clinical performance data, is deemed adequate, provided that either of the following conditions is fulfilled:

   (a) the benefit of the immediate availability on the market of the device outweighs the risk associated with the fact that additional clinical performance data are still required;

   (b) the benefit-risk ratio of the device is favourable and the manufacturer commits to providing additional data from post-market performance follow-up activities.

   Where appropriate, the notified body shall limit the validity of the certificate and specify any conditions for or limitations to the certificate's validity in accordance with Article 51, such as specific post-market performance follow-up activities to be conducted within a specified period of time.

8. The Commission is empowered to adopt delegated acts in accordance with Article 108 in order to amend this Article to adapt to technical and scientific progress and to take into account developments regarding conformity assessment of breakthrough devices or orphan devices at international level.

9. The Commission may, by means of implementing acts, lay down further details of the procedure for the conformity assessment of breakthrough devices or orphan devices set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 48b

Digitalisation of technical documentation, conformity assessment and reports

1. The manufacturer may draw up and make available the technical documentation and any reports or other documents required pursuant to this

Regulation in digital format, in particular structured machine-readable format, provided that it is possible to transform it into human-readable format, and that there is version-control to enable the conduct of retrospective conformity checks. Where the technical documentation, reports or other documents are to be submitted to and assessed by a notified body, the manufacturer shall agree with the notified body on the digital format.

2. Where necessary to ensure that the digital format of the technical documentation, reports or other documents is reliable, interoperable and standardised, the Commission may, by means of CS as referred to in Article 9, lay down minimum requirements or functional specifications for the digital format.';

(31) in Article 49, paragraph 5 of is replaced by the following:

'5. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities in the public interest and with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.';

(32) Article 50 is replaced by the following:

'Article 50

Mechanism for scrutiny of conformity assessments

1. The MDCG or the Commission may, based on reasonable concerns, request advice from an expert panel in relation to the safety and performance of any device. For that purpose, the MDCG or the Commission may request the notified body that issued the certificate for the device in question to submit to the expert panel its performance evaluation assessment report and any subsequent surveillance assessment reports regarding that device. The expert panel may request the notified body or the manufacturer to submit any additional information needed for its assessment.

2. The MDCG or the Commission may, based on reasonable concerns, request advice from one or more EU reference laboratories, on the basis of laboratory testing, in relation to the safety and performance of any device, provided that the device falls within the scope of designation of those EU reference laboratories. For that purpose, the MDCG or the Commission may request the notified body that issued the certificate for the device in question to submit to the EU reference laboratories its performance evaluation assessment report and any subsequent surveillance assessment reports regarding that device. The EU reference laboratories may request the notified body or the manufacturer to submit samples of the device or any additional information needed for their assessment.

3. The notified body shall give utmost consideration to the advice of the expert panel or the EU reference laboratory, as applicable, and, where needed, take any appropriate measures, including those referred to in Article 51(3) and (4)';

(33) Article 51 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

‘1. The notified bodies shall issue certificates in accordance with Annexes IX, X and XI in an official language of the Union and immediately upload them in Eudamed. The minimum content of the certificates shall be as set out in Annex XII.

‘2. The validity of certificates shall not be limited in time, unless in exceptional cases where the notified body considers it necessary to limit the period of validity based on duly justified grounds. In those cases, the notified body shall indicate the period of validity on the certificate. If the period of validity of the certificate is limited, on application by the manufacturer, the notified body may, following an assessment performed in accordance with Annex VII, Section 4.11, extend the validity of the certificate. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.’;

(b) the following paragraph 2a is inserted:

‘2a. During the validity of the certificate, the notified body shall carry out appropriate surveillance activities, including periodic reviews taking into consideration developments of the state of the art. Those reviews shall be proportionate to the risk class of the device.’;

(c) paragraph 3 is replaced by the following:

‘3. Notified bodies may impose conditions on the certificate’s validity, such as limiting the intended purpose of a device or requiring the manufacturer to undertake specific PMPF studies pursuant to Part B of Annex XIII.’;

(d) in paragraph 4, the first sentence is replaced by the following:

‘Where a notified body finds that the requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any conditions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body.’;

(e) in paragraph 5, the first sentence is replaced by the following:

‘The notified body shall enter in the electronic system referred to in Article 52 any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and conditions imposed on certificates.’;

(34) in Article 52, points (f) and (i) are deleted;

(35) Article 54 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. By way of derogation from Article 48, on a duly justified request, any competent authority may authorise for a limited period of time the placing on the market or putting into service within the territory of the Member State concerned of a specific device for which the applicable conformity assessment procedures have not been carried out, provided

the use of that device is in the interest of public health, patient safety or patient health.';

(b) the following paragraph 1a is inserted:

'1a. By way of derogation from Article 6(2) and on a duly justified request, any competent authority may authorise for a limited period of time the provision of a diagnostic or therapeutic service referred to in that Article to a natural or legal person established within the territory of the Member State concerned, using a device for which the applicable conformity assessment procedures set out in this Regulation have not been carried out, provided the provision of such service is in the interest of public health, patient safety or patient health.';

(c) paragraph 2 is replaced by the following:

'2. The Member State shall inform the Commission, the other Member States and the relevant expert panels referred to in Article 106 of Regulation (EU) 2017/745 of any decision to authorise the placing on the market or putting into service of a device, or the provision of a service, in accordance with paragraph 1 or paragraph 1a of this Article, where such authorisation is granted for use other than for a single patient.

The Member State shall make information about such authorisations publicly available.';

(d) in paragraph 3, the first subparagraph is replaced by the following:

'Where a request pursuant to paragraph 1 or paragraph 1a has been submitted to competent authorities in more than one Member State and based on an opinion of an expert panel referred to in Article 106 of Regulation (EU) 2017/745, the Commission, in exceptional cases relating to public health, patient safety or patient health, may, by means of implementing acts, extend for a limited period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 or paragraph 1a of this Article to the territory of the Union, or provide an authorisation referred to in paragraph 1 or paragraph 1a of this Article for the territory of the Union. The Commission may set the conditions under which the device may be placed on the market or put into service, or under which the diagnostic or therapeutic service may be provided. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).';

(e) the following paragraphs 4 and 5 are added:

'4. In the event of a public health emergency at Union level recognised in accordance with Article 23 of Regulation (EU) 2022/2371 of the European Parliament and of the Council*****, the Commission may, by means of implementing acts, on its own initiative after consulting the MDCG, authorise the placing on the market or putting into service of a device in accordance with paragraph 3. The authorisation shall cease to apply at the latest when the recognition of the public health emergency is terminated pursuant to Article 23(2) of Regulation (EU) 2022/2371. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 107(4).

5. The Commission may, by means of implementing acts, lay down rules further specifying the procedure set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

***** Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).';

(36) the following Articles 54a, 54b and 54c are inserted:

'Article 54a

Derogations from certain requirements in the event of a serious cross-border threat to health, disaster or crisis

1. Upon a duly justified request by a manufacturer, a competent authority may authorise for a limited period of time, by way of derogation from the relevant provisions in Annexes II, III, IX, X and XI, an exemption from the requirements related to changes to the manufacturing, design or intended purpose of a CE marked device, where it is in the interest of public health, patient safety or patient health in either of the following circumstances:

   (a) a serious cross-border threat to health as defined in Article 3, point (1) of Regulation (EU) 2022/2371;

   (b) a disaster or a crisis within the meaning of Regulation (EU) ../…. of the European Parliament and of the Council******+.

2. The manufacturer shall ensure that the manufactured devices remain in conformity with the relevant general safety and performance requirements set out in Annex I.

3. The competent authority may request the notified body that issued a certificate for the device in question to assist it in the assessment of the request referred to in paragraph 1.

+ OJ: Please insert in the text the number of the Regulation contained in 2025/0223(COD) (Proposal for a Regulation on the Union Civil Protection Mechanism and Union support for health emergency preparedness and response, and repealing Decision No 1313/2013/EU) and insert the number, date, title and OJ reference of that Regulation in the footnote.

4. Where applicable, the manufacturer shall keep the notified body that issued a certificate for the device in question informed about any changes made regarding the manufacturing, design or intended purpose of a CE marked device in accordance with the authorisation referred to in paragraph 1.

5. Where a request pursuant to paragraph 1 has been submitted to competent authorities in more than one Member State, the Commission, in exceptional cases relating to public health, patient safety or patient health, may, by means of implementing acts, extend for a limited period of time the validity of an exemption granted by a Member State in accordance with paragraph 1 to the territory of the Union, or provide an exemption referred to in paragraph 1 for the territory of the Union. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

   On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 107(4).

****** Regulation (EU) .../... of the European Parliament and of the Council of ... on ... (OJ ..., ELI).

Article 54b

Regulatory sandboxes at national level

1. Member States, on their own initiative or upon a substantiated request by manufacturer or a prospective manufacturer, may establish one or more regulatory sandboxes to which the application of certain requirements of Chapters V or VI or of Annexes I, VIII, IX, X, XI, XIII or XIV would not be appropriate. The Member States shall designate the competent authority that is responsible for the supervision of the regulatory sandbox.

   Member States may also establish regulatory sandboxes jointly with other Member States.

2. The activities within a regulatory sandbox shall take place pursuant to a specific sandbox plan that clearly identify the requirements of this Regulation referred to in paragraph 1, which are temporarily adapted or waived in the regulatory sandbox, a justification that the application of those requirements is not considered to be appropriate and an explanation as to how potential risks related to the adaptation or waiver are to be controlled and mitigated. The plan shall also identify the reasonable duration of the regulatory sandbox necessary to achieve its objectives and the participants in the regulatory sandbox and their respective roles.

3. A regulatory sandbox shall be set up only if the following conditions are met:

   (a) the device is expected to address unmet medical needs or to provide a significant clinical benefit to patients or to the health system compared with similar existing alternatives or the state of the art;

(b) the application of the requirements of this Regulation referred to in paragraph 1 would impede or significantly delay the development of the device and access by healthcare professionals or lay users to such device.

4. The Member State may request an expert panel referred to in Article 106 of Regulation (EU) 2017/745 to provide scientific, technical or regulatory advice on the design of the draft sandbox plan.

5. Any participant in the regulatory sandbox shall, without undue delay, inform the competent authority that is responsible for the supervision of the regulatory sandbox about any harm occurred in relation to the implementation of the regulatory sandbox. The competent authority shall take immediate and adequate corrective measures, including to suspend, revoke or restrict the scope of the regulatory sandbox.

6. Manufacturers and prospective manufacturers participating in a regulatory sandbox shall remain liable under applicable Union and national law for any damage inflicted on third parties as a result of their activities taking place in the regulatory sandbox.

7. The Member State shall inform the Commission and the MDCG about the establishment of a regulatory sandbox and keep them informed about its implementation and outcome.

Article 54c

Union regulatory sandboxes

1. The Commission, on its own initiative or upon a substantiated request by a Member State, may establish by means of implementing acts for a limited time and pursuant to a specific plan, Union regulatory sandboxes, which shall inform whether the existing requirements appropriately regulate a specific type of device with particular characteristics or emerging technologies, and there is a risk that the existing requirements:

   (a) would impede or significantly delay the development of such devices and access by healthcare professionals or patients to those devices; or

   (b) would not adequately protect the health and safety of patients, users or other persons or other aspects of public health.

   Union regulatory sandboxes shall not involve the placing on the market or putting into service of devices which do not comply with this Regulation.

2. The Commission shall request an expert panel referred to in Article 106 of Regulation (EU) 2017/745 to provide scientific, technical or regulatory advice on the design of a Union regulatory sandbox.

3. The Commission shall inform the MDCG about the establishment of a regulatory sandbox and keep it informed about its outcome.

4. The Commission may, by means of implementing acts, specify common principles or the detailed arrangements for the establishment, operation and supervision of regulatory sandboxes pursuant to Article 54b or of Union regulatory sandboxes pursuant to this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

5. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend this Article or Article 54b in order to adapt to scientific, technical or regulatory progress and to take into account developments regarding regulatory sandboxes, including in areas other than *in vitro* diagnostic medical devices.';

(37) in Article 55, the following paragraph 1a is inserted:

'1a. The competent authority of the Member State which issued the certificate of free sale in accordance with paragraph 1 shall make that certificate publicly available in Eudamed.';

(38) Article 56 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Manufacturers shall plan, conduct and document a performance evaluation in accordance with this Article and with Part A of Annex XIII to confirm the safety and performance of the device, in particular those concerning the performance characteristics referred to in Chapter I and Section 9 of Annex I, under normal conditions of use according to the intended purpose of the device, and shall evaluate the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I.

The performance evaluation shall follow a defined and methodologically sound procedure for the demonstration of the following, in accordance with this Article and with Part A of Annex XIII:

(a) scientific validity;

(b) analytical performance;

(c) clinical performance.

The data and conclusions drawn from the assessment of those elements shall constitute sufficient clinical evidence for the device.

The manufacturer shall specify and justify the level of the clinical evidence necessary to confirm the safety and performance of the device. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

The performance evaluation, its results and the clinical evidence derived from it shall be documented in a performance evaluation report as referred to in Section 1.3 of Annex XIII, which shall be part of the technical documentation referred to in Annex II relating to the device concerned.';

(b) paragraphs 2 to 5 are deleted.

(c) paragraph 6 is replaced by the following:

'6. The performance evaluation, its documentation and, where applicable and needed, the summary of safety and performance referred to in Article 29 shall be updated throughout the life cycle of the device concerned with data and findings obtained from implementation of the manufacturer's PMPF plan in accordance with Part B of Annex XIII and the post-market surveillance plan referred to in Article 79, whenever

those data and findings provide information relevant for the confirmation of safety and performance of the device.';

(d) the following paragraph 8 is added:

'8. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend Annex XIII in the light of technical and scientific progress and developments at international level having due regard to the protection of the health and safety of patients, users or other persons and other aspects of public health.';

(39) the following Article 56a is inserted:

'*Article 56a*

Advice from expert panels

For class C and class D devices, a manufacturer may, prior to its performance study or clinical performance evaluation, consult an expert panel as referred to in Article 106 of Regulation (EU) 2017/745, with the aim of reviewing the manufacturer's intended strategy for demonstrating clinical performance or proposals for any clinical performance study. The manufacturer and the notified body involved in any future conformity assessment procedure shall, in the performance evaluation report and the performance evaluation assessment report, give due consideration to the advice of the expert panel, and where they do not follow that advice, they shall provide duly justified reasons.';

(40) Article 58 is amended as follows:

(a) in paragraph 1, point (a) is deleted;

(b) in paragraph 1, point (c) is replaced by the following:

'(c) where the conduct of the study involves additional invasive procedures, including high-risk procedures for collection of specimens, or other risks for the subjects of the studies,';

(c) paragraph 2 is deleted;

(d) in paragraph 5, point (a) is replaced by the following:

'(a) the performance study is the subject of an authorisation by the Member State(s) in which the specimens for the performance study are to be collected, in accordance with this Regulation, unless otherwise stated;';

(41) in Article 64(1), point (b) is replaced by the following:

'(b) there are scientific grounds to expect that participation of the subject in the performance study will have the potential to produce:

(i) a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering or improving the health of the subject, or in the diagnosis of his or her condition; or

(ii) a benefit for the population represented by the subject, provided that the performance study poses only minimal risk to, and imposes minimal burden on, the subject in comparison with the standard treatment of the subject's condition;';

(42) Article 66 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

'The sponsor of a performance study referred to in Article 58(1) and (2) shall enter and submit an application to the Member State(s) in which the specimens for the performance study are to be collected (referred to for the purposes of this Article and Article 71 as 'Member State concerned') accompanied by the documentation referred to in Sections 2 and 3 of Annex XIII and in Annex XIV.';

(b) paragraph 7 is replaced by the following:

'7. The sponsor may start the performance study as soon as the Member State concerned has notified the sponsor of its authorisation and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the performance study. The Member State shall notify the sponsor of the authorisation within 45 days of the validation date of the application referred to in paragraph 5. The Member State may extend this period by a further 20 days for the purpose of consulting with experts.';

(43) in Article 67, paragraph 2 is replaced by the following:

'2. Member States shall ensure that the assessment is done jointly by an appropriate number of persons who collectively have the necessary qualifications and experience.';

(44) in Article 68, the following paragraph 7 is added:

'7. The processing of personal data in the context of a performance study, including the secondary use of personal data initially collected for other studies, shall be deemed to be carried out for scientific research purposes as referred to in Article 9(2), point (j), of Regulation (EU) 2016/679 of the European Parliament and of the Council *******.

*******Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj).';

(45) in Article 70(1), the second and third sentences are replaced by the following:

'The sponsor shall include the documentation referred to in Part A, Section 2, of Annex XIII and in Chapter I, Sections 1, 3 and 4, of Annex XIV. Article 58(5), points (b) to (l) and (p), Article 71(1), Articles 72 and 73, and Article 76(5) and (6), and the relevant provisions of Annexes XIII and XIV shall apply to PMPF studies involving additional invasive or burdensome procedures.';

(46) in Article 71, paragraphs 1 and 2, and paragraph 3, introductory wording and point (a), are replaced by the following:

'1. If a sponsor intends to introduce modifications to a performance study that are likely to have a substantial impact on the safety, health or rights of the subjects

or on the robustness or reliability of the data generated by the study, it shall notify, by means of the electronic system referred to in Article 69, the Member State(s) concerned of the reasons for and the nature of those modifications. The sponsor shall include an updated version of the relevant documentation referred to in Annex XIV as part of the notification. Changes to the relevant documentation shall be clearly identifiable.

2. Where the performance study has been the subject of an authorisation in accordance with Article 58(5), point (a), the Member State shall assess any substantial modification to the performance study in accordance with the procedure laid down in Article 67.

3. The sponsor may implement the modifications referred to in paragraph 1 if the Member State concerned has notified the sponsor of its authorisation, or without such authorisation at the earliest 38 days after the notification referred to in paragraph 1, unless:

(a) the Member State concerned has notified the sponsor of its refusal based on the grounds referred to in Article 67(4) or on considerations of public health, of subject and user safety or health, or of public policy; or';

(47) in Article 73(1), the first sentence is replaced by the following:

'If the sponsor has temporarily halted a performance study or has terminated a performance study early, it shall, within 15 days of the temporary halt or early termination, inform the Member State in which that performance study has been temporarily halted or terminated early, by means of the electronic system referred to in Article 69, providing a justification.';

(48) Article 74 is amended as follows:

(a) in paragraph 4, the second subparagraph is replaced by the following

'The final assessment report shall be taken into account by all Member States concerned when deciding on the sponsor's application in accordance with paragraph 11';

(b) in paragraph 5, the first and second sentence are replaced by the following:

'Each Member State concerned may request, on a single occasion, additional information from the sponsor. The sponsor shall submit the requested additional information within 12 days of receipt of the request.';

(c) in paragraph 6, the words '50 days' are replaced by the words '20 days';

(d) the following paragraph 15 is added:

'15. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend this Article in light of experience gained from the practical application of the coordinated assessment procedure, in particular as regards timelines and the authorisation of performance studies subject to a coordinated assessment.';

(49) Article 75 is deleted;

(50) the following Article 75a is inserted:

'Article 75a

Performance studies in combined studies

Performance studies that are part of combined studies, and which are subject to authorisation in accordance with Article 58, may be carried out in accordance with Article 14c of Regulation (EU) No 536/2014.

If the sponsor chooses to apply Article 14c of Regulation (EU) No 536/2014, the requirements laid down therein and in any implementing and delegated acts adopted in accordance with that Article shall apply in place of the corresponding requirements laid down in this Regulation.';

(51) in Article 78(4), the first sentence is replaced by the following:

'If, in the course of the post-market surveillance, a need for preventive or corrective action, or both, is identified, the manufacturer shall implement the appropriate measures. The competent authorities concerned may request the manufacturer to inform them when such action is taken to reduce a risk that may compromise the safety or performance of the device.';

(52) in Article 79, the second sentence is deleted;

(53) Article 81 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, the first sentence is replaced by the following:

'Manufacturers of class C and class D devices shall prepare a periodic safety update report ('PSUR') for each device, or where relevant, for each category or group of devices, summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 79, together with a description of any preventive and corrective actions taken, including their rationale.';

(ii) the second subparagraph is replaced by the following:

'Manufacturers of class C and class D devices shall update the PSUR in the first year after the certificate is issued and every two years thereafter or when there is a significant change in the benefit-risk determination or in the acceptability of erroneous results. That PSUR shall be part of the technical documentation specified in Annex III.';

(b) paragraph 2 is replaced by the following:

'2. For class D devices, the notified body shall review the PSUR during the surveillance assessment. The manufacturer and notified body shall make such PSURs and the evaluation by the notified body available to the competent authorities through the electronic system referred to in Article 87.';

(54) Article 82 is amended as follows:

(a) in paragraph 1, the second subparagraph is replaced by the following:

'The reports referred to in the first subparagraph shall be submitted without undue delay through the electronic system referred to in Article 87.';

(b) paragraph 3 is replaced by the following:

‘3. Manufacturers shall report any serious incident as referred to in paragraph 1, first subparagraph, point (a), immediately after they have established that there is a causal relationship between that incident and their device or that such causal relationship is reasonably possible, and not later than 30 days after they become aware of the incident.’;

(55) The following Article 82a is inserted:

‘Article 82a

Reporting of actively exploited vulnerabilities and severe incidents related to devices

1. Without prejudice to the reporting obligations regarding serious incidents and field safety corrective actions set out in Article 82, the manufacturer of a device shall report to the computer security incident response teams (‘CSIRTs’), designated as coordinators of the Member States where a device has been made available, and to the European Union Agency for Cybersecurity (ENISA), either of the following:

   (a) any actively exploited vulnerability as defined in Article 3, point (42), of Regulation (EU) 2024/2847 of the European Parliament and of the Council******** contained in the device;

   (b) any severe incident as referred in Article 14(5) of Regulation (EU) 2024/2847 having an impact on the security of the device.

2. The manufacturer shall submit the report referred to in paragraph 1 through the electronic system referred to in Article 87 not later than 30 days after it becomes aware of the actively exploited vulnerability or the severe incident.

3. The report referred to in paragraph 1, as well as any report submitted by a manufacturer in accordance with Article 82 that also qualifies as actively exploited vulnerability or severe incident, shall be made available simultaneously to the CSIRTs designated as coordinators of the Member States in which the device has been made available and to ENISA

4. For the purposes of this Article, the CSIRTs designated as coordinators and ENISA shall have access to Eudamed.

******** Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L, 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).’;

(56) in Article 83(1), the first subparagraph is replaced by the following:

‘Manufacturers shall report by means of the electronic system referred to in Article 87 any statistically significant increase in the frequency or severity of incidents that are not serious incidents, which could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 8 of Annex I or of any significant increase in expected erroneous results established in comparison with the stated performance of the device as referred to in Section 9.1, points (a) and (b), of Annex I and specified in the technical documentation and product information.’;

(57) Article 84 is amended as follows:

(a) in paragraph 1, the second subparagraph is replaced by the following:

'The manufacturer shall cooperate with the competent authorities during the investigations referred to in the first subparagraph and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.';

(b) paragraph 2 is replaced by the following:

'2. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory, or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 82 is evaluated centrally at national level by their competent authority, if possible together with the manufacturer.';

(c) the following paragraph 3a is inserted:

'3a. The competent authority may request the notified body that issued a certificate in accordance with Article 51 for the device in question for assistance in evaluating a corrective action related to a serious incident or a field safety corrective action.';

(d) paragraphs 6 and 7 are replaced by the following:

'6. In the case of a companion diagnostic and where the manufacturer confirms that the serious incident or field safety corrective action may affect the safe and efficient use of the corresponding medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 9 shall inform the national competent authority or the EMA, which was consulted by the notified body in accordance with the procedures set out in Section 5.2 of Annex IX and Section 3, point (k), of Annex X.

7. If, after carrying out the evaluation in accordance with paragraph 3, the evaluating competent authority identifies the need for additional corrective actions from the manufacturer to minimise the risk of recurrence of the serious incident, it shall, through the electronic system referred to in Article 87, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying serious incidents and the outcome of its assessment.';

(e) in paragraph 9, the introductory sentence is replaced by the following:

'The competent authorities shall actively participate in a procedure in order to coordinate their assessments referred to in paragraph 3 whenever such coordination is needed to ensure a high level of protection of the health and safety of patients, users and other persons or the protection of public health throughout the Union, and in particular in the following cases:';

(58) Article 86 is amended as follows:

(a) in the first subparagraph, the reference to 'Articles 80 to 85 and 87' is replaced by 'Articles 79 to 85 and 87';

(b) in the first subparagraph, point (b) is replaced by the following:

‘(b) the reporting of serious incidents and field safety corrective actions and field safety notices, and the provision and content of the post-market surveillance plan, periodic summary reports, post-market surveillance reports, PSURs and trend reports by manufacturers as referred to in Articles 79, 80, 81, 82, 83 and 84 respectively;’;

(59) in Article 87(2), second sentence, the reference to ‘Article 49’ is replaced by ‘Article 51’;

(60) Article 88 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices and on the compliance of economic operators with the obligations set out in this Regulation including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.’;

(b) the following paragraph 1a is inserted:

‘1a. Member States shall ensure that their national competent authorities are provided with adequate and sufficient technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation.’;

(c) paragraph 2 is replaced by the following:

‘2. The competent authorities shall draw up annual surveillance activity plans, taking into account the European market surveillance programme, which shall be developed and maintained by the MDCG, and local circumstances.’;

(d) the following paragraph 12 is added:

‘12. In respect of devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, the competent authorities shall cooperate with market surveillance authorities of their Member State designated in accordance with Article 70 of Regulation (EU) 2024/1689.’:

(61) Article 89 is replaced by the following:

‘Article 89

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

The competent authorities of a Member State, either alone or in cooperation with the competent authorities of other Member States, shall carry out an evaluation of a device or of an economic operator covering the relevant requirements laid down in this Regulation relating to the risk presented by the device or to any other non-compliance of the device or of the economic operator, where they, based on data

obtained by vigilance or market surveillance activities or on other information, have reason to believe either of the following:

(a) a device may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(b) a device or an economic operator otherwise does not comply with the requirements laid down in this Regulation.

The relevant economic operators and, where applicable and requested, the notified body that issued a certificate for the device in question shall cooperate with the competent authorities.';

(62) Article 90 is amended as follows:

(a) paragraph 3 is replaced by the following:

'3. The economic operators referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken within the period referred to in that paragraph throughout the Union in respect of all the devices concerned that they have made available on the market.';

(b) paragraph 7 is amended as follows:

(i) the first sentence is replaced by the following:

'Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of the notified measures taken by a Member State, those measures shall be deemed to be justified.';

(ii) the following subparagraph is added:

'Paragraph 4 shall not apply to such measures adopted by the Member States.';

(63) Article 91 is amended as follows:

(a) in paragraph 1, the third sentence is deleted;

(b) in paragraph 2, the first subparagraph is replaced by the following:

'Where the Commission considers the national measure to be justified as referred to in paragraph 1 of this Article, Article 90(7), second sentence, shall apply. If the Commission considers the national measure to be unjustified, the Member State concerned, as well as any Member State that has taken corresponding restrictive or prohibitive measures, shall withdraw the measure.';

(64) Article 92 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Where, having performed an evaluation pursuant to Article 89, the competent authorities of a Member State find that a device or an economic operator does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a

reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.';

(b) in paragraph 2, the first sentence is replaced by the following:

'Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1, the Member State concerned shall, without delay, take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the national market.';

(c) the following paragraph 2a is inserted:

'2a. The economic operator shall take any appropriate corrective action pursuant to paragraph 1 or paragraph 2 throughout the Union in respect of all the devices concerned that they have made available on the market, unless a competent authority takes other appropriate measures.';

(65) in Article 93(3), the fourth sentence is deleted;

(66) the heading of Chapter VIII is replaced by the following:

'***COOPERATION BETWEEN MEMBER STATES AND EU REFERENCE LABORATORIES***';

(67) in Article 96, the first and second sentences are replaced by the following:

'The Member States shall designate the competent authority or authorities responsible for the implementation and practical application of this Regulation. They shall ensure that those authorities are entrusted with sufficient powers, resources, equipment and knowledge necessary for the effective and efficient performance of their tasks pursuant to this Regulation';

(68) in Article 97, paragraph 2 is deleted;

(69) Articles 98 and 99 are deleted;

(70) Article 100 is amended as follows:

(a) paragraph 2 is amended as follows:

(i) point (a) is replaced by the following:

'(a) to verify the performance claimed by the manufacturer and the compliance of class D devices with the applicable CS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in Section 4.9 of Annex IX and in Section 3, point (j), of Annex X;';

(ii) point (d) is replaced by the following:

'(d) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices, where requested on the basis of comparative test results or other studies';

(iii) points (e) and (j) are deleted;

(iv) the following subparagraph is added:

'The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend the first subparagraph by adding, adapting or removing tasks from the list of tasks of the EU reference laboratories.';

(b) paragraph 3 is deleted;

(c) in paragraph 4, point (b) is replaced by the following:

'(b) have at their disposal the necessary equipment and reference material to carry out the tasks assigned to them';

(d) in paragraph 5, point (j) is deleted;

(e) paragraph 7 is replaced by the following:

'7. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they may be required to pay fees to wholly or partially cover the costs incurred by that laboratory in carrying out its tasks according to predetermined and transparent terms and conditions.';

(71) Article 101 is deleted;

(72) Article 103 is amended as follows:

(a) in paragraph 1, the reference to 'Directive 95/46/EC' is replaced by 'Regulation (EU) 2016/679';

(b) in paragraph 2, the reference to 'Regulation (EC) No 45/2001' is replaced by 'Regulation (EU) 2018/1725 of the European Parliament and of the Council*********.

********* Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).';

(73) the following Article 103a is inserted:

'Article 103a

Submission of information or documents

The submission of information or documents in accordance with this Regulation shall take place electronically. ';

(74) Article 104 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. This Regulation shall be without prejudice to the possibility for Member States and the Commision to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost-recovery principles.';

(b) in paragraph 2, second sentence, the words 'on request' are deleted;

(75) Article 105 is deleted;

(76) in Article 108(6), first and second sentences, the words 'three months' are replaced by the words 'two months';

(77) Article 109 is deleted;

(78) in Article 110, the following paragraphs 12 and 13 are added:

'12. By way of derogation from Article 5 and from paragraphs 3 to 3e of this Article, a device as referred to in paragraph 3a or paragraph 3b of this Article that meets the criteria for an orphan device set out in Article 48a(3) may be placed on the market or put into service beyond the dates referred to in paragraphs 3a and 3b if the following conditions are met:

(a) an expert panel referred to in Article 106 of Regulation (EU) 2017/745 has issued an opinion confirming the fulfilment of the criteria for an orphan device set out in Article 48a(3);

(b) there are no significant changes to the design and intended purpose of the device;

(c) the device does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

The requirements of this Regulation, with the exception of Chapters IV, V and VI, shall apply to the device referred to in the first subparagraph. By way of derogation from Article 81(1), manufacturers of class C and class D devices placed on the market or put into service in accordance with this paragraph shall update the PSUR at least annually. On an annual basis, the manufacturer shall submit the PSUR and, where applicable, an update of the summary of safety and performance to the competent authority of the Member State in which it is established.

The competent authority of the Member State may require the manufacturer to conduct defined post-market surveillance or PMPF activities within a specified period of time to generate additional data to confirm the safety and performance of the device and to evaluate the acceptability of the benefit-risk ratio.

Devices placed on the market or put into service in accordance with this paragraph, which do not have a valid certificate in accordance with paragraph 2, shall not bear the CE marking. In its EU declaration of conformity, the manufacturer shall make reference to the fact that the device is an orphan device placed on the market or put into service in accordance with this paragraph.

The manufacturer shall inform the intended users that the device is an orphan device placed on the market or put into service in accordance with this paragraph, where applicable, in the summary of safety and performance and in the instructions for use or any other accompanying documentation.

At least every 10 years, the manufacturer shall request an opinion from an expert panel referred to in Article 106 of Regulation (EU) 2017/745 confirming the fulfilment of the criteria for an orphan device set out in Article 48a(3) of this Regulation.

13. As regards devices for which a conformity assessment procedure is pending on …[*OP please insert the date = six months after the date of entry into force of this Regulation*] or for which a certificate is issued by a notified body before that date, the manufacturer and the notified body may agree to continue

applying the provisions of this Regulation in the form applicable before …[*OP please insert the date = six months after the date of entry into force of this Regulation*] until the conformity assessment procedure is finalised or until the certificate is renewed.';

(79) Article 111 is amended as follows:

(a) in the first sentence, the date '27 May 2027' is replaced by the date …'[OP, please insert the date = five years after the date of entry into force of this Regulation]';

(b) the second sentence is deleted;

(80) in Article 113(3), point (f), the following subparagraph is added:

'After the date of application of the provisions referred to in the first subparagraph of this point, where Member States maintain national databases, the relevant information available in Eudamed for those national databases shall be retrieved from Eudamed.';

(81) Annexes I, II, III, VI, VII, IX, X, XI, XII, XIII, and XIV to Regulation (EU) 2017/746 are amended in accordance with Annex II to this Regulation.

Article 3

Amendments to Regulation (EU) 2022/123

Article 30 of Regulation (EU) 2022/123 is amended as follows:

(1) the first subparagraph is replaced by the following:

'The Agency shall provide the secretariat for the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745 (the 'expert panels') and shall provide the support necessary to ensure that those expert panels can efficiently perform the tasks set out in that Regulation and in Regulation (EU) 2017/746.';

(2) the second subparagraph is amended as follows:

(a) the introductory wording is replaced by the following: 'The Agency shall, in particular,':

(b) point (a) is replaced by the following:

'(a) select and appoint the experts in accordance with Article 106(2) and (5) of Regulation (EU) 2017/745 and provide administrative and technical support to the expert panels for the provision of opinions and advice;';

(c) points (c), (d) and (e) are replaced by the following:

'(c) ensure that the work of the expert panels is carried out in an independent manner in accordance with Article 106(3) and Article 107 of Regulation (EU) 2017/745. For that purpose, the Agency shall establish systems and procedures to actively manage and prevent potential conflicts of interest;

(d) maintain and regularly update a webpage for the expert panels and make all necessary information not already publicly available in Eudamed publicly available on that webpage;

(e) publish the opinions of the expert panels in accordance with Regulation (EU) 2017/745 or Regulation (EU) 2017/746, while ensuring confidentiality in accordance with Article 109 of Regulation (EU) 2017/745 or Article 102 of Regulation (EU) 2017/746;';

(d) in point (f), the reference to 'Article 106(14)' is replaced by the reference to 'Article 106(10)';

(e) the following point (i) is added:

'(i) submit to the Commission a substantiated recommendation for the fees to be paid by manufacturers or notified bodies for the opinions or advice provided by expert panels, as referred to in Article 106(9) and (10) of Regulation (EU) 2017/745.'.

Article 4

Amendments to Regulation (EU) 2024/1689

Annex I to Regulation (EU) 2024/1689 is amended as follows:

(1) in Section A, points 11 and 12 are deleted;

(2) in Section B, the following points are added:

'21. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p.1);

22. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).'.

Article 5

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2. It shall apply from …[OP please insert the date = six months after the date of entry into force of this Regulation].

3. By way of derogation from paragraph 2:

(a) Article 1, points (47) and (95), Article 2, points (33), (40) and (78), Article 3 and Article 4 shall apply from …[OP please insert the date = the date of entry into force of this Regulation];

(b) Article 1, points (27) to (40) and Article 2, points (24), (25) and (26), shall apply from… [OP please insert the date = 12 months after the date of entry into force of this Regulation];

(c) Article 1, point (69), and Article 2, point (55), shall apply from …[OP please insert the date = three years after date of entry into force of this Regulation];

(d) Article 1, point (15), shall apply from …[OP please insert the date = five years after the date of entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg,

For the European Parliament	*For the Council*
The President	*The President*

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1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

1.2. Policy area(s) concerned

Competitiveness, prosperity and security

1.3. Objective(s)

1.3.1. General objective(s)

Simplify the rules on medical devices and *in vitro* diagnostic medical devices, reduce the administrative burden on manufacturers, and enhance the predictability and cost-efficiency of the certification procedure by notified bodies, while preserving a high level of public health protection and patient safety.

In doing so, these measures will support the growth and development of companies -- boosting their competitiveness and their contribution to European welfare and prosperity - and promote a more favorable business environment that reduces administrative burdens and strengthens companies' ability to innovate, create jobs, and drive economic growth, fostering a high level of patients' care.

1.3.2. Specific objective(s)

Specific objective 1: To increase the cost-effectiveness and overall competitiveness of the EU medical devices and *in vitro* diagnostic medical devices industry by supporting innovation (including through adaptive regulatory pathways for breakthrough technologies, and through further digitalisation), while ensuring a high level of protection of human health for patients and users.

Specific objective 2: To simplify and streamline certain requirements and procedures for medical devices and *in vitro* diagnostic medical devices identified as particularly burdensome and disproportionate, especially for low and medium risk devices and for orphan devices.

Specific objective 3: Improve the coordination between national competent authorities, Commission/EMA and Notified Bodies, i.e. the governance and organisation of the EU regulatory system, and enable the EU medical devices sector to benefit from international cooperation including reliance mechanisms.

1.3.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The proposal aims to improve the functioning of the current regulatory framework, in particular with regard to the smooth functioning of the internal market, while ensuring a high level of health protection for patients.

It builds on the existing key features of the framework, notably the decentralised approach with responsibilities allocated to the Member States and the involvement of Notified Bodies in the conformity assessment procedure. The aim of this revision is to ensure a leaner and more cost-effective regulatory framework and further strengthen the existing level of harmonisation, creating a more competitive and innovative EU market.

The impact of the current proposal is expected to materialise on several actors.

Manufacturers

- Benefit from increased legal clarity and certainty through clearer scope and definitions, including published outcomes of classification disputes.
- Operate under a more flexible and proportionate framework for clinical evaluation and clinical investigations (expert panel advice, proportionate clinical updates, use of non-clinical data, clearer rules for vulnerable populations).
- Face simplified and less burdensome classification and conformity assessment procedures, supporting innovation (e.g. dedicated pathways for breakthrough devices, regulatory sandboxes).
- Benefit from streamlined re-certification procedures and reduced associated costs.
- Experience reduced administrative burden in post-market surveillance, vigilance and market surveillance.
- Gain access to expert panels for early advice, improving predictability (with some additional costs/time).
- SMEs benefit from more proportionate fees and tailored support schemes, including support offered by the EMA.

Notified Bodies

- Benefit from improved legal clarity and certainty due to clearer scope and definitions.
- Operate within a more efficient and predictable regulatory system.
- May experience adjustment of fee revenues due to simplified procedures, and a more streamlined framework reducing complexity and administrative load.

Distributors

• Gain from clearer obligations and improved legal certainty.
• Benefit from more stable and reliable supply chains due to reduced risks of device shortages.
• Face lower administrative burden thanks to streamlined procedures.

National Competent Authorities

• Gain from clearer scope, definitions and legal certainty.
• Benefit from simplified governance structures, reinforced coordination mechanisms and international cooperation.
• Achieve more efficient oversight through clearer procedures.

Patients, users and healthcare systems

• Benefit from sustained availability of safe, high-quality and innovative devices.
• Increased availability of information on the regulatory process
• Experience reduced risks of shortages, securing continuity of care.
• Gain from improved public health outcomes due to safety, availability and innovation.

1.3.4. Indicators of performance

– Sustained availability of critical devices (target: no shortages due to regulatory causes) (measure availability and continuity of supply)
– Reduced time for conformity assessment
– Reduced administrative burden for manufacturers (target: measurable annual reduction).
– Increased number of innovative devices entering the market
– Maintain the availability of orphan devices and devices intended for small size populations.
– Stable or improved safety indicators (no increase in serious incidents).
– Improved predictability and consistency in regulatory decisions (e.g. number of expert panel opinions).
– Higher SME participation in the EU medical device market (support to SMEs for the use of the EU regulatory framework).
– Use of dedicated pathways for breakthrough devices (measure the support for innovation)
– Participation in international cooperation mechanisms

1.4. The proposal/initiative relates to:

☐ a new action

☐ a new action following a pilot project / preparatory action[52]

☒the extension of an existing action

☐ a merger or redirection of one or more actions towards another/a new action

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

The adoption of the Regulation by the co-legislators is expected for Q2 2027. It will enter into force on 20th day following that of its publication in the OJEU. Transitional periods are foreseen for those measures that require procedural or technical adaptations by manufacturers to ensure a smooth transition to the modified regulatory framework.

1.5.2. Added value of EU involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this section 'added value of EU involvement' is the value resulting from EU action, that is additional to the value that would have been otherwise created by Member States alone.

Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices aimed to establish a robust, transparent, predictable and sustainable regulatory framework for medical and *in vitro* diagnostic devices, ensuring a high level of safety and health whilst supporting innovation. They have been applicable since 26 May 2021 and 26 May 2022 respectively.

However, the much more demanding requirements stemming from these Regulations, including for existing devices, combined with the limited capacities of notified bodies and the insufficient preparedness of manufacturers, have resulted in the risk of shortages and even the disappearance of critical devices from the market. In practice, these challenges have revealed that certain elements of the Regulations themselves created structural obstacles that the system has been unable to absorb.

Consequently, the transitional periods have been repeatedly extended, yet these extensions have provided only short-term relief and could not address the underlying issues embedded in the current regulatory framework. To resolve these structural problems and to achieve a streamlined, predictable and future-proof system, coordinated action at EU level is required through this proposed act.

[52] As referred to in Article 58(2), point (a) or (b) of the Financial Regulation.

1.5.3. Lessons learned from similar experiences in the past

This proposal stems from the results of the targeted evaluation.

1.5.4. Compatibility with the multiannual financial framework and possible synergies with other appropriate instruments

• The initiative will be fully financed via redeployments from programmes under the 2028-2034 MFF. • Strategic Projects that address a vulnerability in the supply chains of critical medicinal devices will be deemed to contribute to the STEP objectives and may benefit from facilitation of the financial support when granted the STEP seal on the basis of Regulation (EU) 2024/795 establishing the Strategic Technologies for Europe Platform (STEP).

1.5.5. Assessment of the different available financing options, including scope for redeployment

n/a

1.6. Duration of the proposal/initiative and of its financial impact

☐ **limited duration**

– ☐ in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☒**unlimited duration**

– Implementation with a start-up period from YYYY to YYYY,

– followed by full-scale operation.

1.7. Method(s) of budget implementation planned[53]

☒ **Direct management** by the Commission

– ☒ by its departments, including by its staff in the Union delegations;

– ☒ by the executive agencies

☐ **Shared management** with the Member States

☒ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated

– ☐ international organisations and their agencies (to be specified)

– ☐ the European Investment Bank and the European Investment Fund

– ☒ bodies referred to in Articles 70 and 71 of the Financial Regulation

– ☐ public law bodies

– ☐ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees

– ☐ bodies or persons entrusted with the implementation of specific actions in the common foreign and security policy pursuant to Title V of the Treaty on European Union, and identified in the relevant basic act

– ☐ bodies established in a Member State, governed by the private law of a Member State or Union law and eligible to be entrusted, in accordance with

[53] Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: https://myintracomm.ec.europa.eu/corp/budget/financial-rules/budget-implementation/Pages/implementation-methods.aspx.

sector-specific rules, with the implementation of Union funds or budgetary guarantees, to the extent that such bodies are controlled by public law bodies or by bodies governed by private law with a public service mission, and are provided with adequate financial guarantees in the form of joint and several liability by the controlling bodies or equivalent financial guarantees and which may be, for each action, limited to the maximum amount of the Union support.

Comments

The budget will be implemented by the European Commission, by HaDEA and by the European Medicines Agency (EMA).

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

All Union agencies work under a strict monitoring system involving an internal control coordinator, the Internal Audit Service of the Commission, the Management Board, the Commission, the Court of Auditors and the Budgetary Authority. This system is reflected and laid down in the EMA's founding regulation. In accordance with the Joint Statement on the EU decentralised agencies (the 'Common Approach'), the framework financial regulation (2019/715) and related Commission Communication C(2020)2297, the annual work programme and Single Programming Document of the Agency comprise detailed objectives and expected results, including a set of performance indicators. The Single Programming Document combines multiannual and annual programming as well as "strategy documents", e.g. on independence. DG SANTE comments through the Agency's Management Board and prepares a formal Commission Opinion on the Single Programming Document. The activities of the Agency will be measured against these indicators in the Consolidated Annual Activity Report. The Agency will monitor periodically the performance of its internal control system to ensure that data is collected efficiently, effectively and timely and to identify internal control deficiencies, register and assess the results of controls, control deviations and exceptions. The results of the internal control assessments, including significant weaknesses identified and any differences as compared to internal and external audit findings will be disclosed in the Consolidated Annual Activity report.

2.2. Management and control system(s)

2.2.1. Justification of the budget implementation method(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

The annual EU subsidy will be transferred to the Agency in accordance with its payment needs and upon its request. The Agency will be subject to administrative controls including budgetary control, internal audit, annual reports by the European Court of Auditors, the annual discharge for the execution of the EU budget and possible investigations conducted by OLAF to ensure, in particular, that the resources allocated to the Agency are put to proper use. Through its representation in the Agency's Management Board and Audit Committee, the Commission will receive audit reports and will ensure that adequate actions are defined and timely implemented by the Agency to address the issues identified. All payments will remain pre-financing payments until the Agency's accounts have been audited by the European Court of Auditors and the Agency has submitted its final accounts. If necessary, the Commission will recover unspent amounts of the instalments paid to the Agency. The activities of the Agency will also be subject to the supervision of the Ombudsman in accordance with Article 228 of the Treaty. These administrative controls provide a number of procedural safeguards to ensure that account is taken of the interests of the stakeholders.

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

The main risks relate to the Agency's performance and independence in implementing the tasks entrusted to it. Underperformance or impaired independence could hamper the achievement of the objectives of this initiative and also reflect negatively on the Commission's reputation. The Commission and the Agency have put in place internal procedures that aim at covering the risks identified above. The internal procedures are in full compliance with the Financial Regulation and include anti-fraud measures and cost-benefit considerations. First and foremost, sufficient resources should be made available to the Agency in both financial and staffing terms to achieve the objectives of this initiative. Furthermore, quality management will include both the integrated quality-management activities and risk-management activities within the Agency. A risk review is conducted annually, with risks being assessed at a residual level, i.e. taking into account controls and mitigations already in place. Conducting self-assessments (as part of the EU Agencies benchmarking programme), annual reviews of sensitive functions and ex-post controls also fall within this area, as does maintaining a register of exceptions. To preserve impartiality and objectivity in every aspect of the Agency's work, a number of policies and rules on management of competing interests have been put in place and will be regularly updated, describing specific arrangements, requirements and processes applying to the Agency's Management Board, scientific committee members and experts, the Agency's staff and candidates, as well as consultants and contractors. The Commission will be informed in a timely manner of relevant management and independence issues encountered by the Agency and will react upon notified issues in a timely and adequate manner.

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio between the control costs and the value of the related funds managed), and assessment of the expected levels of risk of error (at payment & at closure)

The Commission's and the Agency's internal control strategies take into consideration the main cost drivers, and the efforts already taken over several years to reduce the cost of controls, without compromising the effectiveness of controls. The existing control systems proved to be able to prevent and/or to detect errors and/or irregularities, and in case of errors or irregularities, to correct them. In the past five years, the Commission's yearly costs of controls under indirect management represented less than 1% of the annual budget spent on subsidies paid to the Agency. The Agency allocated less than 0,5% of its total annual budget on control activities centering around integrated quality management, audit, anti-fraud measures, finance and verification processes, corporate risk management and self-assessment activities.

2.3. Measures to prevent fraud and irregularities

As for its activities in indirect management, the Commission shall take appropriate measures ensuring that the financial interests of the European Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of

the amounts wrongly paid and, where appropriate, by effective, proportional and deterrent penalties. To this effect, the Commission adopted an anti-fraud strategy, latest update of April 2019 (COM(2019)196)[54], covering preventive, detective and corrective measures. The Commission or its representatives and the European Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds. OLAF shall be authorised to carry out on-the-spot checks and inspections on economic operators concerned indirectly by such funding. As regards the European Medicines Agency, the anti-fraud measures are provided for in Article 69 of Regulation (EC) No 726/2004 and the framework financial Regulation (2019/715). The Executive Director and the Management Board of the Agency will take the appropriate measures in accordance with the Internal Control Principles applied across all EU institutions. In line with the Common Approach and Article 42 of the framework financial Regulation, an anti-fraud strategy has been developed and is followed by the Agency. The Agency's Anti-fraud strategy covers 3-year period and is accompanied by a corresponding action plan, outlining both specific focus areas and actions for the next years, and several continuous actions that are carried out every year, such as a specific standalone fraud risk assessment, with the identified fraud risks included in the overall Agency risk register. Anti-fraud trainings are organised as part of the induction training and via mandatory anti-fraud e-learning training for newcomers. Staff are made aware of how to report any suspects of wrongdoings and disciplinary procedures are in place as per the rules of the Staff Regulations.

54 Commission Anti-Fraud Strategy: enhanced action to protect the EU budget.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[55]	from EFTA countries [56]	from candidate countries and potential candidates [57]	From other third countries	other assigned revenue
2	Operational expenditure	Diff	YES	YES	YES	NO
2	Support expenditure	Non-diff.	YES	YES	YES	NO
2	Union contribution to the European Medicines Agency	Non-diff.	YES	YES	YES	NO
4	Headquarters and Representation offices - officials and temporary staff	Non-diff.	NO	NO	NO	NO
4	External personnel – Headquarters and Representation offices	Non-diff.	NO	NO	NO	NO
4	Conference and meeting costs	Non-diff.	NO	NO	NO	NO
4	Missions, conferences and representation expenses	Non-diff.	NO	NO	NO	NO

[55] Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
[56] EFTA: European Free Trade Association.
[57] Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ☒ The proposal/initiative requires the use of operational appropriations, as explained below

Amounts are indicative and do not prejudge the outcome of the ongoing negotiations on the next MFF.

3.2.1.1. Appropriations from voted budget

EUR million (to three decimal places)

Heading of multiannual financial framework		Number	2								
DG: <SANTE.>			Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028-2034**	**POST 2024**
Operational appropriations											
TBA	Commitments	(1a)	0,297	0,303	0,309	0,315	0,322	0,328	0,335	**2,210**	0,335
	Payments	(2a)	0,059	0,209	0,303	0,309	0,315	0,321	0,694	**2,210**	0,694
Appropriations of an administrative nature financed from the envelope of specific programmes											
Support expenditure		(3)	**1,010**	**1,010**	**1,010**	**1,010**	**1,010**	**1,010**	**1,010**	**7,070**	**1,010**
TOTAL appropriations	Commitments	=1a+1b+3	**1,307**	**1,313**	**1,319**	**1,325**	**1,332**	**1,338**	**1,345**	**9,280**	**1,345**
for DG <SANTE>	Payments	=2a+2b+3	**1,069**	**1,219**	**1,313**	**1,319**	**1,325**	**1,331**	**1,704**	**9,280**	**1,704**

* Figures in the table above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

EUR million (to three decimal places)

[Agency]: <EMA>	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028 - 2034	POST 2034(annual expenditure)
TBA / Union contribution to the European Medicines Agency	**3,209**	**4,689**	**4,782**	**4,878**	**4,976**	**5,075**	**5,177**	**32,785**	**5,280**

Without prejudice to the negotiations on the next MFF, the appropriations allocated to the agency from 2028 onwards will be compensated via redeployments from applicable programmes of the same heading as the agency under the 2028-2034 MFF. If a compensatory reduction is needed, the resources allocated to the agencies and their funding streams may need to be revised.

			Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2028-2034	POST 2034 Annual expenditure
TOTAL operational appropriations (including contribution to decentralised agency)	Commitments	(4)	3,506	4,992	5,092	5,193	5,297	5,403	5,511	**34,995**	5,615
	Payments	(5)	3,268	4,898	5,085	5,187	5,290	5,396	5,870	**34,995**	5,974

TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	1,010	1,010	1,010	1,010	1,010	1,010	1,010	7,070	**1,010**
TOTAL appropriations under HEADING <SANTE> of the multiannual financial framework	Commitments	=4+6	**4,516**	**6,002**	**6,102**	**6,203**	**6,307**	**6,413**	**6,521**	**42,065**	**6,6256**
	Payments	=5+6	**4,278**	**5,908**	**6,095**	**6,197**	**6,300**	**6,406**	**6,880**	**42,065**	**6,984**

* Figures in the table above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

Heading of multiannual financial framework	4	'Administrative expenditure'[58]

VOTED APPROPRIATIONS	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028 - 2034	POST 2034(annual expenditure)
HEADING 4									
Human resources	2,820	2,820	2,820	2,820	2,820	2,820	2,820	**19,740**	2,820
Other administrative expenditure	0,108	0,110	0,113	0,115	0,117	0,120	0,122	**0,805**	0,122
Subtotal HEADING 4	**2,928**	**2,930**	**2,933**	**2,935**	**2,937**	**2,940**	**2,942**	**20,545**	**2,942**
Outside HEADING 4									
Human resources	1,010	1,010	1,010	1,010	1,010	1,010	1,010	**7,070**	1,010
Other expenditure of an administrative nature	0,000	0,000	0,000	0,000	0,000	0,000	0,000	**0,000**	0,000
Subtotal outside HEADING 4	**1,010**	**1,010**	**1,010**	**1,010**	**1,010**	**1,010**	**1,010**	**7,070**	**1,010**
TOTAL	**3,938**	**3,940**	**3,943**	**3,945**	**3,947**	**3,950**	**3,952**	**27,615**	**3,952**

* Figures in the table above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

[58] The necessary appropriations should be determined using the annual average cost figures available on the appropriate BUDGpedia webpage.

EUR million (to three decimal places)

TOTAL HEADING 1 to 4									
		Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2028-2034
TOTAL appropriations under HEADINGS 1 to 4	Commitments	**7,444**	**8,932**	**9,034**	**9,138**	**9,244**	**9,353**	**9,463**	**62,610**
of the multiannual financial framework	Payments	**7,207**	**8,838**	**9,028**	**9,132**	**9,238**	**9,346**	**9,822**	**62,610**

* Figures in the table above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

3.2.2. Estimated output funded from operational appropriations

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs			**Year**		**Year**		**Year**		**Year**		**Year**		**Year**		**Year**		**TOTAL 2028-2034**		**POST**	
⇩			**2028**		**2029**		**2030**		**2031**		**2032**		**2033**		**2034**				**2034**	
	OUTPUTS																			
	Type	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost
SPECIFIC OBJECTIVE No 1, No 2 and No3																				
- Eudamed-maintenance and adaptation of the system to the new requirements				0,297		0,303		0,309		0,315		0,322		0,328		0,335		**2,210**		0,335
Subtotal for specific objective No 1				**0,297**		**0,303**		**0,309**		**0,315**		**0,322**		**0,328**		**0,335**		**2,210**		**0,335**
TOTALS				**0,297**		**0,303**		**0,309**		**0,315**		**0,322**		**0,328**		**0,335**		**2,210**		**0,335**

* Figures in the table above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

3.2.3. Summary of estimated impact on administrative appropriations

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☒ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below

3.2.3.1. Appropriations from voted budget

VOTED APPROPRIATIONS	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028 - 2034	POST 2034 Annual expenditure)
HEADING 4									
Human resources	2,820	2,820	2,820	2,820	2,820	2,820	2,820	**19,740**	2,820
Other administrative expenditure	0,108	0,110	0,113	0,115	0,117	0,120	0,122	**0,805**	0,122
Subtotal HEADING 4	**2,928**	**2,930**	**2,933**	**2,935**	**2,937**	**2,940**	**2,942**	**20,545**	**2,942**
Outside HEADING 4									
Human resources	1,010	1,010	1,010	1,010	1,010	1,010	1,010	**7,070**	1,010
Other expenditure of an administrative nature	0,000	0,000	0,000	0,000	0,000	0,000	0,000	**0,000**	0,000
Subtotal outside HEADING 4	**1,010**	**1,010**	**1,010**	**1,010**	**1,010**	**1,010**	**1,010**	**7,070**	**1,010**
TOTAL	**3,938**	**3,940**	**3,943**	**3,945**	**3,947**	**3,950**	**3,952**	**27,615**	**3,952**

* Figures in the table above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

The appropriations required for human resources and other expenditure of an administrative nature cannot be met by redeployment within DG SANTE and will be met by redeployement within the Commission under the annual allocation procedure and in the light of budgetary constraints.

3.2.4. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources

– ☒ The proposal/initiative requires the use of human resources, as explained below

3.2.4.1. Financed from voted budget

Estimate to be expressed in full-time equivalent units (FTEs)[59]

VOTED APPROPRIATIONS	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	POST 2034
• Establishment plan posts (officials and temporary staff)								
20 01 02 01 (Headquarters and Commission's Representation Offices)	15	15	15	15	15	15	15	15
20 01 02 03 (EU Delegations)	0	0	0	0	0	0	0	0
01 01 01 01 (Indirect research)	0	0	0	0	0	0	0	0
01 01 01 11 (Direct research)	0	0	0	0	0	0	0	0
Other budget lines (specify)	0	0	0	0	0	0	0	0
• External staff (in Full Time Equivalent unit: FTE)								
20 02 01 (AC, END from the 'global envelope')	0	0	0	0	0	0	0	0
20 02 03 (AC, AL, END and JPD in the EU Delegations)	0	0	0	0	0	0	0	0
Admin. Support line [XX.01.YY.YY] [2] - at Headquarters	0	0	0	0	0	0	0	0
Admin. Support line [XX.01.YY.YY] [2] - in EU Delegations	0	0	0	0	0	0	0	0
01 01 01 02 (AC, END - Indirect research)	0	0	0	0	0	0	0	0
01 01 01 12 (AC, END - Direct research)	0	0	0	0	0	0	0	0
Other budget lines (specify) - Heading 4	0	0	0	0	0	0	0	0
Other budget lines (Support Credits budget line of the Health programme) - Outside Heading 4	10	10	10	10	10	10	10	10
TOTAL	**25**	**25**	**25**	**25**	**25**	**25**	**25**	**25**

[59] Please specify below the table how many FTEs within the number indicated are already assigned to the management of the action and/or can be redeployed within your DG and what are your net needs.

Considering the overall strained situation in Heading 4, in terms of both staffing and the level of appropriations, the human resources required will be met by staff from the DG who are already assigned to the management of the action and/or have been redeployed within the DG or other Commission services.

The internal staff (15 FTEs) required to implement the proposal (in FTEs) will be covered with additional staff to be financed under heading 4. The additional external staff(10 FTEs) will be financed from the Support expenditure of the programme budget line.

	To be covered by current staff available in the Commission services	**Exceptional additional staff***		
		To be financed under Heading 4 or Research	**To be financed from BA line**	**To be financed from fees**
Establishment plan posts		15	N/A	
External staff (CA, SNEs, INT)			10	

* The tasks included in the proposal at stake cannot be covered fully by existing HR resources and internal redeployments within DG SANTE because the existing resources are already allocated to tasks stemming from the current legislative framework and cannot therefore be redeployed. Moreover, new different profiles will be needed for the implementation of the proposal.

Description of tasks to be carried out by:

Officials and temporary staff	1. Additional 13 FTEs (5 AD + 2 AST + 6 CA FG IV) will be needed to support joint assessments of notified bodies, the new joint monitoring activities and enhanced coordination efforts. 2. Additional 12 FTEs (8 AD and 4 CA FG IV) are needed to secure implementation, in view of the stronger EU oversight of Notified Bodies and other relevant regulatory activities (i.e. strengthening coordination, delegated and implementing acts, activities of the NBO Working Group to resolve divergent opinions and disputes, participation in international/reliance programmes, the resolution of qualification and classification disputes).
External staff	Please see above

3.2.5. Overview of estimated impact on digital technology-related investments

Compulsory: the best estimate of the digital technology-related investments entailed by the proposal/initiative should be included in the table below.

Exceptionally, when required for the implementation of the proposal/initiative, the appropriations under Heading 4 should be presented in the designated line.

The appropriations under Headings 1-3 should be reflected as "Policy IT expenditure on operational programmes". This expenditure refers to the operational budget to be used to re-use/ buy/ develop IT platforms/ tools directly linked to the implementation of the initiative and their associated investments (e.g. licences, studies, data storage

etc). The information provided in this table should be consistent with details presented under Section 4 "Digital dimensions".

TOTAL Digital and IT appropriations	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2028 - 2034
HEADING 4								
IT expenditure (corporate)	0	0	0	0	0	0	0	**0**
Subtotal HEADING 4	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Outside HEADING 4								
Policy IT expenditure on operational programmes	0,297	0,303	0,309	0,315	0,322	0,328	0,335	2,210
Subtotal outside HEADING 4	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
TOTAL	0,297	0,303	0,309	0,315	0,322	0,328	0,335	2,210

***** Figures in the table above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

3.2.6. Compatibility with the current multiannual financial framework

The proposal/initiative:

– ☒ can be fully financed through redeployment within the relevant heading of the multiannual financial framework (MFF)

The initiative will be fully financed via redeployments from programmes under the 2028-2034 MFF.[60]

3.2.7. Third-party contributions

The proposal/initiative:

– ☒ does not provide for co-financing by third parties

– ☐ provides for the co-financing by third parties estimated below:

60

Appropriations in EUR million (to three decimal places)

	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	Total
Specify the co-financing body								
TOTAL appropriations co-financed								

3.2.8. Estimated human resources and the use of appropriations required in a decentralised agency

Staff requirements (full-time equivalent units)

[Agency]: <EMA>	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	POST **2034(annual number)**
Temporary agents (AD Grades)	5	5	5	5	5	5	5	5
Temporary agents (AST grades)	3	3	3	3	3	3	3	3
Temporary agents (AD+AST) subtotal	*8*	*8*	*8*	*8*	*8*	*8*	*8*	*8*
Contract staff	16	16	16	16	16	16	16	16
Seconded National Experts								
Contract agents and SNE subtotal	*16*	*16*	*16*	*16*	*16*	*16*	*16*	*16*
TOTAL staff	**24**	**24**	**24**	**24**	**24**	**24**	**24**	**24**

Appropriations covered by the EU budget contribution in EUR million (to three decimal places)

[Agency]:	Year	Year	Year	Year	Year	Year	Year	**TOTAL**	POST

<EMA>	2028	2029	2030	2031	2032	2033	2034	2028 - 2034	2034(annual expenditure)
Title 1: Staff expenditure	1,808	3,688	3,762	3,837	3,914	3,992	4,072	**25,075**	4,154
Title 2: Infrastructure and operating expenditure								**0,000**	
Title 3: Operational expenditure	1,401	1,000	1,020	1,041	1,061	1,083	1,104	**7,710**	1,126
TOTAL of appropriations covered by the EU Budget	**3,209**	**4,698**	**4,782**	**4,878**	**4,976**	**5,075**	**5,177**	**32,785**	**5,280**

* Figures in the table above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

Appropriations covered by fees, if applicable, in EUR million (to three decimal places)

[Agency]: <EMA>	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028 - 2034	POST 2034(annual expenditure)
Title 1: Staff expenditure								**0,000**	
Title 2: Infrastructure and operating expenditure								**0,000**	
Title 3: Operational expenditure		0,600	0,610	0,650	0,750	0,770	0,800	**4,180**	0,816
TOTAL of appropriations covered by fees	**0,000**	**0,600**	**0,610**	**0,650**	**0,750**	**0,770**	**0,800**	**4,180**	**0,816**

* Figures in the table above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

Overview/summary of human resources and appropriations (in EUR million) required by the proposal/initiative in a decentralised agency

[Agency]:	Year	Year	Year	Year	Year	Year	Year	TOTAL	POST

<EMA>	2028	2029	2030	2031	2032	2033	2034	2028 - 2034	2034(annual expenditure)
Temporary agents (AD+AST)	8	8	8	8	8	8	8		8
Contract agents	16	16	16	16	16	16	16		16
Seconded National Experts	0	0	0	0	0	0	0		
Total staff	24	24	24	24	24	24	24		24
Appropriations covered by the EU Budget	3,209	4,689	4,782	4,878	4,976	5,075	5,177	**32,785**	5,280
Appropriations covered by fees	0,000	0,600	0,610	0,650	0,750	0,770	0,800	**4,180**	0,816
Appropriations co-financed (if applicable)	0,000	0,000	0,000	0,000	0,000	0,000	0,000	**0,000**	0,000
TOTAL appropriations	**3,209**	**5,289**	**5,392**	**5,528**	**5,726**	**5,845**	**5,977**	**36,965**	**6,096**

Temporary staff and External staff

1. EMA-related expenses: This component covers the financial needs for additional FTEs at the EMA, which will be entrusted with new or expanded tasks, such as managing an increasing number of expert panels and new responsibilities for monitoring shortages of devices, including the establishment and maintenance of a list of critical devices.

This amounts to **additional 24 FTEs**, to cover the above-mentioned additional activities that will be delegated to the Agency:

a. 11 FTEs for expert panels following the opening of scope to IVDs and all class III devices (2 AD, 2 AST and 6 CA FG IV and 1 CA FG II)

b. 9 FTEs for governance (10 FTEs for increased coordination of National Competent Authorities in specific areas and 2 FTEs for SME office to support manufacturers) (2 AD, 1 AST and 6 CA FG IV)

c. 4 FTEs for Article 10a(4) (IT system to monitor shortages, implementation of changes to database) and Article 10a(5) (establish and manage a list of critical devices) (1 AD and 3 CA FG IV)

* Figures in the table above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

3.3. Estimated impact on revenue

– ☒ The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

  – ☐ on own resources

  – ☐ on other revenue

  – ☐ please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[61]						
		Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**
Article …								

For assigned revenue, specify the budget expenditure line(s) affected.

[…]

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

[61] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20% for collection costs.

4. DIGITAL DIMENSIONS

Premise: MDR and IVDR are already characterised by digital relevance with the introduction of the European database on medical devices (Eudamed), an interconnected IT system composed of six modules, to store data relating to the entire life cycle of devices placed on the EU market. Eudamed not only enhances transparency and traceability, but it is also an essential tool for all actors involved to comply with the Regulations. Four out of six modules of Eudamed are complete. This database/system will facilitate further digitalisation of the medical device sector, it will bring an important potential for digitalisation and harmonisation.

The amending Regulation introduces simplification measures as well as new reporting obligations, hence it has an impact on the modules of Eudamed already developed.

Starting from this assumption, for what concerns Eudamed, the below table has been drafted considering the impact/delta on the already finalised modules of the provisions introduced by the Proposal.

4.1. Requirements of digital relevance

Reference to the requirement (MDR/IVDR)	Requirement description	Actors affected or concerned by the requirement	High level processes	Categories
Art. 10a(4) (MDR/IVDR)	The Commission, if needed in cooperation with the EMA, shall set up, maintain and manage an IT platform for reporting and information exchange on interruption or discontinuation of supply of devices	Economic operators Member States competent authorities	Market surveillance	Data Digital solution Digital public service
Art. 18(1) MDR	Manufacturer can provide implant card information in electronic or digital format	Economic operators	Traceability Labelling	Data

Art. 19(2a) MDR / Art 17(2a) IVDR	Declaration of conformity may be provided in electronic form	Economic operators	Conformity of the device	Data
Art 30(2) MDR / Art 27(2) IVDR	National databases on distributors shall retrieve device information from Eudamed	Member States competent authorities Distributors	Registration of distributors	Data Digital service
Art. 52b MDR / Art 48b IVDR	Digitalisation of conformity assessment: in agreement with notified bodies, the manufacturer can provide the technical documentation in digital format and any reports or document for the purposes of the conformity assessment procedures.	Manufacturers Notified bodies	Conformity assessment	Data Digital service
Art. 60 MDR / Art 55 IVDR	(Eudamed) Certificates of free sales shall be made available in Eudamed by the competent authority	Competent authorities	Transparency	Data Digital service
Art 87a (2) MDR / Art 82a (2) IVDR	Reporting of actively exploited vulnerabilities and severe incidents of connected devices	Manufacturers Member States competent authorities CSIRTs designated as coordinators and ENISA	Cybersecurity	Data
Art 106b(5) MDR	EMA access to Eudamed	EMA	EMA support	Data Digital service
Art 110a MDR / Art 103a IVDR	Submission of information or documents electronically	All having such obligation under the MDR	Submission of information/documents	Digital service

Annex I section 23.1(c) MDR / Annex I section 20.1(c) IVDR	Labels may be provided in digital form to the extent of implementing rules adopted pursuant to the MDR	Economic operators	Labelling	Digital public service
Annex VI Part A sections 1.2 and 1.3 (MDR/IVDR) and Part B section 13 MDR / section 10 IVDR	Contact details including digital contact	Economic operators	Communication	Data
Annex VI Part B section 37 MDR / section 29 IVDR	Provide instruction for use in electronic format or URL of the website where it is available	Manufacturers	Instruction for use availability	Data Digital public service

4.2. Data

Reference to the requirement (MDR/IVDR)	Type of data	Standard and/or Specification (if applicable)
Art. 10a(4) (MDR/IVDR)	Data on possible shortages of devices	
Art. 18(1) MDR	Data on implantable devices	
Art. 19(2a) MDR / Art 17(2a) IVDR	Data on conformity of the device	
Art 30(2) MDR / Art 27(2) IVDR	Device data	In accessible formats; free of charge in a clear, comprehensive, user-friendly and easily accessible way. Download in XML format. Publicly available
Art. 52b MDR / Art 48b IVDR	Technical documentation of the device	
Art. 60 MDR / Art 55 IVDR	Data on certificates of free sales	In accessible formats; free of charge in a clear, comprehensive, user-friendly and easily accessible way. Download in XML format. Publicly available
Art 87a (2) MDR / Art 82a (2) IVDR	Data on actively exploited vulnerabilities and severe incidents of connected devices	In accessible formats; free of charge in a clear, comprehensive, user-friendly and easily accessible way. Upload/download in XML format
Art 106b(5) MDR	Eudamed data	In accessible formats; free of charge in a clear, comprehensive, user-friendly and easily accessible way.

Art 110a MDR / Art 103a IVDR	Documentation on devices	
Annex I section 23.1(c) MDR / Annex I section 20.1(c) IVDR	Data on labels of devices	
Annex VI Part A sections 1.2 and 1.3 (MDR/IVDR) and Part B section 13 MDR / section 10 IVDR	Contact details	
Annex VI Part B section 37 MDR / section 29 IVDR	Data on instruction for use of devices	

Alignment with European Data strategy

The proposal aligns with the Data strategy since it promotes the further digitalisation compared to MDR and IVDR of certain processes such as the transmission, by manufacturers to notified bodies, of technical documentation and other relevant documents; it includes, in Eudamed, new elements such as the certificates of free sales and the devices' instructions for use , thereby further expanding the publicly available data; additionally, it simplifies certain workflows that need to be carried out in Eudamed, thus facilitating systems' use for the actors involved.

Eudamed: the Commission is data controller and processor.

No link to European health data space (EHDS).

Once-only principle

N/A as the once-only principle was already included in MDR/IVDR with the creation of Eudamed. The proposal now only builds on that, but the original compliance with this principle was already in the original Regulations.

Data flows

Type of data	Reference(s) to the requirement(s)	Actors who provide the data	Actors who receive the data	Trigger for the data exchange	Frequency (if applicable)
Implant card including in electronic or digital format	Articles 18(1) MDR	Economic operators	Patients, Healthcare professionals, Competent authorities	Product control/traceability	
EU declaration of conformity	Art 19(2a) MDR, Article 17(2a) IVDR	Economic operators	Patients, Healthcare professionals, Competent authorities	Conformity of the device	
Device data	Art 30(2) MDR / Art 27(2) IVDR	Economic operators	Member States competent authorities	Product control	
Certificates of free sales	Article 60 MDR, Article 55 IVDR	Competent authorities	Public	Product control	
Product technical documentation for conformity assessment in electronic form	Article 52b MDR, Article 48b IVDR	Economic operators	Competent authorities Notified bodies	Product control Conformity assessment	
Information on actively exploited vulnerabilities and severe incidents of connected devices	Art 87a (2) MDR / Art 82a (2) IVDR	Manufacturers	Member States competent authorities CSIRTs designated as coordinators and ENISA	Cyber security issue/incident	
Data on possible shortages of devices	Article 10a MDR, Article 10a IVDR	Economic operators	Competent authorities health institutions and	Reporting obligation Product control	

			healthcare professionals		

4.3. Digital solutions

Digital solution	Type of data	Reference(s) to the requirement(s)	Main mandated functionality	Responsible body	How is accessibility catered for?	How is reusability considered?	Use of AI?
IT platform	Data on shortages of devices	Article 10a MDR, Article 10a IVDR	Allow economic operators to provide information on possible shortages of devices	EMA	The relevant Accessibility Directive[62] provisions will be mentioned in the technical specifications	Single platform for reporting	N/A
Document in electronic format	Implant card, declaration of conformity	Articles 18(1), 19(2a) MDR, Article 17(2a)	N/A	N/A	N/A	N/A	N/A

[62] Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (OJ L 151, 7.6.2019, pp. 70–115, ELI: http://data.europa.eu/eli/dir/2019/882/oj)

		IVDR					
National electronic system	Device information	Art 30(2) MDR / Art 27(2) IVDR	Retrieval of device data from Eudamed's relevant electronic system	Member States competent authorities	The relevant Accessibility Directive provisions will be mentioned in the technical specifications	Data retrieved from Eudamed and not re-provided by economic operators in national systems	N/A
Electronic system in Eudamed	Certificates of free sales	Article 60 MDR, Article 55 IVDR	Allow upload of certificates of free sales and make them available to the public	COM	The relevant Accessibility Directive provisions will be mentioned in the technical specifications	Single platform for reporting	N/A
Document in electronic format	Product technical documentation for conformity assessment in electronic form	Article 52b MDR, Article 48b IVDR	N/A	N/A	N/A	N/A	N/A
Electronic system in Eudamed	Data on cyber security incidents and vulnerabilities	Art 87a (2) MDR / Art 82a (2) IVDR	Allow reporting by economic operator of	COM	The relevant Accessibility Directive provisions	Single platform for reporting	N/A

	of medical devices		cyber security incidents and vulnerabilities		will be mentioned in the technical specifications		
Electronic systems in Eudamed	Data on medical devices	Art 106b (5) MDR	Allow EMA to access Eudamed electronic systems data	COM	The relevant Accessibility Directive provisions will be mentioned in the technical specifications	N/A	N/A
Document in electronic format	Documentation on medical devices	Art 110a MDR / Art 103a IVDR	N/A	N/A	N/A	N/A	N/A
Document in electronic format	Data on labels	Annex I section 23.1(c) MDR / Annex I section 20.1(c) IVDR	N/A	N/A	N/A	N/A	N/A

Digital solution #1: EUDAMED

Digital and/or sectorial policy (when these are	**Explanation on how it aligns**

applicable)	
AI Act	Shall be considered in delegated and implementing acts.
EU Cybersecurity framework	Shall be considered in delegated and implementing acts, including the compliance with Regulation (EU) 2024/2847.
eIDAS	Shall be considered in delegated and implementing acts.
Single Digital Gateway and IMI	Shall be considered in delegated and implementing acts.
Others	

Digital solution #2: IT Platform (if chosen as alternative to Eudamed for the purposes of Article 10a)

Digital and/or sectorial policy (when these are applicable)	**Explanation on how it aligns**
AI Act	Shall be considered in delegated and implementing acts.
EU Cybersecurity framework	Shall be considered in delegated and implementing acts, including the compliance with Regulation (EU) 2024/2847.
eIDAS	Shall be considered in delegated and implementing acts.
Single Digital Gateway and IMI	Shall be considered in delegated and implementing acts.
Others	

4.4. Interoperability assessment

High-level description of the digital public service(s) affected by the requirements

Digital public service or category of digital public services	**Description**	**Reference(s) to the requirement(s)**	**Interoperable Europe Solution(s)** **(NOT APPLICABLE)**	**Other interoperability solution(s)**
Medical Devices Conformity Assessment	Manufacturers are allowed to transmit conformity assessment documentation in digital format	MDR Article 52b, IVDR Article 48b	NA	This solution will facilitate future interoperability
Eudamed	European database on medical devices	MDR Article 33, IVDR Article 30	NA	Currently interoperable with national databases and with economic operators systems (data exchange via machine to machine)

Impact of the requirement(s) as per digital public service on cross-border interoperability

Digital public services : Medical Devices Conformity Assessment and Eudamed

Assessment	Measure(s)	Potential remaining barriers (if applicable)
Alignment with existing digital and sectorial policies		
Organisational measures for a smooth cross-border digital public services delivery	Extended role of European Medicines Agency	
Measures taken to ensure a shared understanding of the data **Please list such measures**	Reuse of Eudamed data model already defined and established by previous version of MDR/IVDR	
Use of commonly agreed open technical specifications and standards **Please list such measures**	N/A for the new requirements	

4.5. Measures to support digital implementation

Description of the measure	Reference(s) to the requirement(s)	Commission role (if applicable)	Actors to be involved (if applicable)	Expected timeline (if applicable)
The Commission will make use of ICT procurement to set up the necessary functionalities in Eudamed and may adopt implementing/delegated acts to further define details on the implementation of the relevant requirements/articles	Articles 60, 87a, 106b(5) MDR, Articles 55, 82a(2) IVDR	The Commission shall set up the functionalities and adopt such acts if necessary.	EMA Economic operators Member states competent authorities	
The Commission or EMA may make use of ICT procurement to set up the necessary functionalities in the IT platform	Article 10a MDR, Article 10a IVDR	The Commission will facilitate the necessary synergies with Eudamed	Economic operators Healthcare institutions Healthcare professionals Member states competent authorities	

EUROPEAN
COMMISSION

Strasbourg, 16.12.2025
COM(2025) 1023 final

ANNEXES 1 to 2

ANNEXES

to the

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

{SWD(2025) 1050 final} - {SWD(2025) 1051 final} - {SWD(2025) 1052 final}

ANNEX I

Annexes I, II, III, VI, VII, VIII, IX, X, XI, XII, XIII, XIV and XV to Regulation (EU) 2017/745 are amended as follows:

(1) Annex I is amended as follows:

(a) Section 10.6 is replaced by the following:

’10.6. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials as defined in Commission Recommendation C/2022/3689*.

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* Commission Recommendation of 10 June 2022 on the definition of nanomaterial (OJ C 229, 14.6.2022, pp. 1).`;

(b) Section 13 is amended as follows:

(i) Section 13.1. is replaced by the following:

’13.1. For devices manufactured utilising derivatives of substances of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with Article 1(6), point (g), the following shall apply:

(a) donor registration, donor review, collection and testing of the substances of human origin shall be done in accordance with Regulation (EU) 2024/1938;

(b) processing, preservation and any other handling of those substances of human origin or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process;

(c) the traceability system for those devices shall be complementary to and compatible with the traceability and data protection requirements laid down in Regulation (EU) 2024/1938.’;

(ii) in Section 13.2., point (c) is replaced by the following:

‘(c) in the case of devices manufactured utilising tissues or cells of animal origin or their derivatives, as referred to in Regulation (EU) No 722/2012, the particular requirements laid down in that Regulation, or in any subsequent implementing rules adopted pursuant to this Regulation, shall apply.’;

(c) Section 17.4. is replaced by the following:

‘17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics, IT security measures and

cybersecurity, including protection against unauthorised access, necessary to run the software as intended.';

(d) Section 23.1. is amended as follows:

(i) in the first subparagraph, the second sentence is replaced by the following:

'Such information may appear on the device itself, on the packaging or in the instructions for use, taking into account the following:';

(ii) in point (c), the following sentence is added:

'Labels may be provided in digital form to the extent, and only under the conditions, set out in any implementing rules adopted pursuant to this Regulation.';

(iii) in point (f), the reference to 'Regulation (EU) No 207/2012' is replaced by the reference to 'Commission Implementing Regulation (EU) 2021/2226**'

** Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices (OJ L 448, 15.12.2021, p. 32, ELI: http://data.europa.eu/eli/reg_impl/2021/2226/oj)';

(iv) the following point (i) is added:

'(i) For a device that is exclusively in use with a medicinal product in accordance with Article 19 of [Proposal for a Directive on the Union code relating to medicinal products for human use, and repealing Directive 2011/83/EC and Directive 2009/35/EC] and packaged together with a medicinal product, the instructions for use may be included, where needed, as part of the co-packaging of the medicinal product with the device. Moreover, the information on the label of the device may be limited to the particulars referred to in Section 23.2, points (a) and (c), where, following agreement of the competent authority responsible for the authorisation of the medicinal product, the following conditions are met:

– the information necessary for safe use and correct functioning of the device is provided to the user with the summary of product characteristics and/or package leaflet of the medicinal product under the responsibility of the marketing authorisation holder set out in [Proposal for a Directive on the Union code relating to medicinal products for human use, and repealing Directive 2011/83/EC and Directive 2009/35/EC];

– the traceability and identification of the device is ensured by the marketing authorisation holder.';

(e) Section 23.2. is amended as follows:

(i) in point (e), the second and third indents are replaced by the following:

– ‘substances of human origin or their derivatives, or

– tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 or in any subsequent implementing rules adopted pursuant to this Regulation’;

(ii) point (o) is deleted;

(iii) in point (q), the first sentence is replaced by the following:

‘an indication that the device is a medical device or an accessory for a medical device’;

(f) in Section 23.4., point (s), the fourth indent is replaced by the following:

– ‘if the device is intended to administer medicinal products, substances of human origin or tissues or cells of animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered,’;

(2) Annex II is amended as follows:

(a) Section 6.1. is amended as follows:

(i) the heading of Section 6.1. is replaced by the following:

‘**6.1. Non-clinical, pre-clinical and clinical data**’;

(ii) point (a) is replaced by the following:

‘(a) results of tests, such as engineering, laboratory, *in vitro*, *ex vivo*, *in silico* testing, computational modeling, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications;’;

(iii) point (c) is replaced by the following:

‘(c) the clinical evaluation plan, the clinical evaluation report and its updates referred to in Article 61(1) and Part A of Annex XIV.’;

(iv) point (d) is deleted;

(b) Section 6.2. is amended as follows:

(i) in point (b), the first sentence is replaced by the following:

‘(b) Where a device is manufactured utilising substances of human origin or tissues or cells of animal origin, or their derivatives, and is covered by this Regulation in accordance with Article 1(6), points (f) and (g), and where a device incorporates, as an integral part, substances of human origin or their derivatives that have an action ancillary to that of the device and is covered by this Regulation in accordance with Article 1(10), first subparagraph, a statement indicating this fact.’;

(ii) the following point (h) is added:

‘(h) Where the device incorporates as an integral part an *in vitro* diagnostic medical device that has an action ancillary to that of the device, as referred to in Article 1(7) of this Regulation, the

documentation shall include the results of the assessment of the conformity of the *in vitro* diagnostic medical device part with the relevant general safety and performance requirements set out in Annex I to Regulation (EU) 2017/746 contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the *in vitro* diagnostic medical device. Where those results of the conformity assessment are not available and where for the conformity assessment of the *in vitro* diagnostic medical device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/746, an opinion on the conformity of the *in vitro* diagnostic medical device part with the relevant general safety and performance requirements set out in Annex I to Regulation 2017/746 issued by a notified body designated in accordance with that Regulation for the type of device in question shall be included in the documentation.';

(3) in Annex III, Section 2 is replaced by the following:

'2. The PSUR referred to in Article 86 or the post-market surveillance report referred to in Article 85.';

(4) Annex VI is amended as follows:

(a) Parts A and B are replaced by the following:

'PART A

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLE 31

Manufacturers and where applicable, authorised representatives, and, where applicable, importers and, where applicable the persons referred to in Article 22(1) shall submit the following information relating to the economic operator:

1. type of economic operator (manufacturer, authorised representative, importer or the person referred to in Article 22(1)),
2. name, address and contact details, including the digital contact, of the economic operator,
3. where submission of information is carried out by another person on behalf of any of the economic operators mentioned under Section 1.1, the name, address and contact details, including the digital contact, of that person,
4. name, address and contact details, including the digital contact, of the person or persons responsible for regulatory compliance referred to in Article 15.

PART B

CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE IN ACCORDANCE WITH ARTICLES 28 AND 29

The manufacturer shall provide to the UDI database the following information relating to the manufacturer and the device:

1. Basic UDI-DI as referred to in Article 27 and any additional UDI-DIs,
2. For devices referred to in Article 120(3), type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body and the link to the information that appears on the certificate and was entered by the notified body in the electronic system on notified bodies and certificates,
3. Member State in which the device is to be or has been placed on the market in the Union,
4. Member States where the device is or is to be made available,
5. risk class of the device,
6. presence of a substance which, if used separately, may be considered to be a medicinal product and name of that substance,
7. presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma and name of this substance,
8. presence of tissues or cells of human origin, or their derivatives (y/n),
9. presence of tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 or any subsequent implementing rules adopted pursuant to that Regulation (y/n),
10. where applicable, the single identification number of the clinical investigation or investigations conducted in relation to the device or a link to the clinical investigation registration in the electronic system on clinical investigations,
11. in the case of devices listed in Annex XVI, specification as to whether the intended purpose of the device is other than a medical purpose,
12. in the case of devices designed and manufactured by another legal or natural person as referred in Article 10(15), the name, address and contact details, including the digital contact, of that legal or natural person,
13. where applicable, the summary of safety and clinical performance,
14. status of the device (placed on the market, no longer placed on the market, recalled, field safety corrective action initiated).
15. quantity per package configuration,
16. the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number),
17. if applicable, the unit of use UDI-DI (where a UDI is not labelled on the device at the level of its unit of use, a ‘unit of use’ DI shall be assigned so as to associate the use of a device with a patient),
18. name and address of the manufacturer (as indicated on the label),
19. the SRN issued in accordance with Article 31(2),
20. if applicable, name and address of the authorised representative (as indicated on the label),

21. the medical device nomenclature code as provided for in Article 26,

22. if applicable, name or trade name, and if applicable additional trade names,

23. if applicable, device model, reference, or catalogue number,

24. if applicable, clinical size (including volume, length, gauge, diameter),

25. additional product description (optional),

26. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),

27. labelled as a single-use device (y/n),

28. if applicable, the maximum number of reuses,

29. device labelled sterile (y/n),

30. need for sterilisation before use (y/n),

31. containing latex (y/n),

32. where applicable, information labelled in accordance with Section 10.4.5 of Annex I,

33. if applicable, the instructions for use, or where available, the URL of the website where the instructions for use are made available,

34. if applicable, critical warnings or contra-indications.'

(b) Part C is amended as follows:

(i) in Section 1, the definition of 'Basic UDI-DI' is replaced by the following:

'Basic UDI-DI

The Basic UDI-DI is the primary identifier of a device model. The Basic UDI-DI is the main key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) to connect devices with the same intended purpose, risk class and essential design and manufacturing characteristics. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.';

(ii) in Section 4.10, the second sentence is replaced by the following:

'The UDI carrier for reusable devices that require cleaning, disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device, unless the device is intended to be reused exclusively by or for the same patient.';

(5) Annex VII is amended as follows:

(a) in Section 1.1.1., the following sentence is added:

'It shall also include information about the larger organisation to which the notified body belongs.';

(b) Section 1.1.2. is replaced by the following:

‘1.1.2. If the notified body is a legal entity that is part of a larger organisation, the activities of that organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented. In such cases, the requirements of Section 1.2 are applicable to both the notified body and the larger organisation to which it belongs. The larger organisation and any of the legal entities belonging to it shall not be involved in the design, manufacture, marketing, installation or maintenance of the devices for which the notified body is designated or offer consultancy services for such activities, neither shall they represent the parties engaged in such activities.’;

(c) in Section 1.2.9., the following sentence is added:

‘The notified body shall have documented procedures in place to offer and carry out dialogues with the manufacturer before and after an application for conformity assessment is lodged.’;

(d) Section 1.3.1. is replaced by the following:

‘1.3.1. The notified body shall have documented procedures in place ensuring that its personnel, committees, branch offices, subsidiaries, subcontractors, and any associated body or personnel of external bodies respect the confidentiality of the information which comes into its possession during the performance of conformity assessment activities, except when disclosure is required by law.’;

(e) in Section 1.4.2., the second sentence is deleted;

(f) the following Section 1.4.3. is inserted:

’1.4.3. By way of derogation from Section 1.4.1, the notified body may demonstrate coverage for liability through adherence to a guarantee fund that provides effective protection and is recognised by the Member State(s) concerned.’;

(g) Section 1.6.1. is replaced by the following:

‘1.6.1. The notified body shall participate in the activities of the notified body coordination group referred to in Article 49 and ensure that its assessment and decision-making personnel are informed of all relevant legislation, standards, guidance and best practice documents adopted in the framework of this Regulation.’;

(h) Section 2.1. is replaced by the following:

‘2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and is capable of supporting and demonstrating in the most efficient manner the consistent fulfilment of the requirements of this Regulation.’ ;

(i) Section 2.3. is replaced by the following:

‘2.3. The top-level management of the notified body shall ensure that the quality management system is fully understood, implemented and maintained throughout the notified body organisation, including branch offices, subsidiaries and subcontractors involved in conformity assessment activities pursuant to this Regulation.’;

(j) Section 3.2.3. is amended as follows:

(i) the first sentence is replaced by the following:

'3.2.3. The personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities shall not be external experts or be subcontracted.';

(ii) the sixth indent is replaced by the following:

– 'adequate experience in conformity assessments under this Regulation, Regulation (EU) 2017/746 or previously applicable law within a notified body.'

(k) in Section 3.2.4., the first sentence is replaced by the following:

'The notified body shall have permanent availability of personnel with relevant clinical expertise.';

(l) in Section 3.2.7., the first sentence is replaced by the following:

'The personnel with overall responsibility for final reviews and decision-making on certification shall not be external experts or be subcontracted.';

(m) in Section 3.4.1., first paragraph, the following sentence is added:

'They shall inform the manufacturer accordingly.';

(n) in Section 4.1., the second paragraph is replaced by the following:

'The requirements laid down in Sections 4.3, 4.4, 4.7 and 4.8 shall not be subcontracted or fulfilled by external experts.';

(o) in Section 4.2.(a), the second sentence is replaced by the following:

'That description shall include which languages are acceptable for submission of documentation and for any related correspondence and the modalities for carrying out the dialogue referred to in Section 1.2.9 before an application is lodged;';

(p) in Section 4.5.1., the second subparagraph is amended as follows:

(i) the ninth indent is replaced by the following:

– 'in the case of class IIa or class IIb devices, assess the technical documentation of the representative device(s);';

(ii) the eleventh indent is deleted;

(iii) the following indents are added:

– 'where appropriate, perform a rolling review of the manufacturer's data or documentation as they become available;

– in case of class I devices that are placed on the market in sterile condition, have measuring function or are reusable surgical instrument, assess the quality management system only in relation to the relevant special aspects of these devices;

– leverage evidence from previous assessments performed.';

(q) Section 4.5.2.(a) is amended as follows:

(i) the introductory wording is replaced by the following:

'(a) As part of the assessment of the quality management system, a notified body shall prior to or in relation with an audit and in accordance with its documented procedures:';

(ii) the fourth indent is replaced by the following:

– 'clearly identify, for class IIa and class IIb devices, the representative devices selected for the assessment of technical documentation as referred to in Annexes II and III,';

(r) in Section 4.5.2.(b), the second paragraph is replaced by the following:

'The documentation shall be sampled in such a manner as to reflect the risks associated with the intended use of the device, the complexity of the manufacturing technologies, the range and classes of devices produced or under certification and any available post-market surveillance information.';

(s) in Section 4.5.4(a), the second indent is replaced by the following:

– 'the pre-clinical testing, for example laboratory, *in vitro*, *ex vivo*, *in silico* testing, simulated use testing, computer modelling, the use of animal models;';

(t) in Section 4.5.5., third paragraph, the following indent is added:

– where applicable, the justification for the confirmation of the safety and performance that is based on the results of non-clinical testing methods alone,';

(u) in Section 4.5.6., the second paragraph is replaced by the following:

'In the case of devices manufactured utilising tissues or cells of animal origin or their derivatives, such as from transmissible spongiform encephalopathy (TSE) susceptible species, as referred to in Regulation (EU) No 722/2012, or in any subsequent implementing rules adopted pursuant to this Regulation, the notified body shall have documented procedures in place that fulfil the requirements laid down in Regulation (EU) No 722/2012 or those subsequent implementing rules.';

(v) in Section 4.6., second paragraph, the introductory wording is replaced by the following:

'The report(s) of the notified body shall:';

(w) Section 4.8. is amended as follows:

(i) the first sentence is replaced by the following:

'The notified body shall have documented procedures for decision-making including as regards the allocation of responsibilities for the issuance, suspension, limitation and withdrawal of certificates.'.;

(ii) the third sentence is amended as follows:

(1) the fourth indent is replaced by the following:

– 'decide whether conditions or limitations need to be defined for the certification,';

(2) the fifth indent is replaced by the following:

– ‘where appropriate, decide, based on the novelty, risk classification, clinical evaluation and conclusions from the risk analysis of the device, on a period of certification,’;

(3) the eighth indent is replaced by the following:

– ‘issue a certificate or certificates in accordance with the minimum requirements laid down in Annex XII and indicate whether there are conditions or limitations associated with the certification,’;

(x) Section 4.9. is amended as follows:

(i) the third indent is replaced by the following:

– ‘the intended purpose of or claims made for the device,’;

(ii) the second paragraph is replaced by the following:

‘The procedures and contractual arrangements referred to in the first paragraph shall clearly distinguish between changes that do not need to be reported, that need to be reported without requiring prior approval and that require prior approval.’;

(iii) in the third paragraph, the introductory sentence is replaced by the following:

‘In accordance with its documented procedures, the notified body in question shall, where changes require prior approval:’;

(iv) the following paragraph is added:

‘Where appropriate, the notified body and the manufacturer shall agree on a predetermined change control plan enabling the manufacturer to implement changes in accordance with such a plan without prior information.’;

(y) Section 4.10. is amended as follows:

(i) in the first paragraph, the second and third indents are replaced by the following:

– for screening relevant sources of scientific and clinical data and post-market information relating to the scope of their designation. That screening shall be conducted in the framework of the coordination group established in Article 49 to avoid unnecessary duplication and to enhance efficiency and work-sharing. The findings from the screening shall be taken into account in the planning and conduct of surveillance activities,

– to assess whether any reported serious incident related to a serious public health threat or any field safety corrective action taken or envisaged by the manufacturer or required of it by a competent authority has an impact on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented.’;

(ii) the second paragraph is amended as follows:

(1) the introductory wording is replaced by the following:

‘The notified body in question shall, with regard to signals arising from vigilance data to which they have access under Article 92(2), decide which of the following options to apply, where appropriate:’;

(2) the first indent is deleted;

(iii) the third paragraph is amended as follows:

(1) the first indent is replaced by the following:

– ‘conduct surveillance audits of the manufacturer which shall be planned and conducted in line with the relevant requirements in Section 4.5,’;

(2) the eighth indent is replaced by the following:

– ’where necessary, impose conditions or limitations on the relevant certificate, or suspend or withdraw it.’;

(iv) in the fourth paragraph, the third indent is replaced by the following:

– ‘ensure that the clinical evaluation, as most recently updated, is appropriately reflected in the instructions for use and, where applicable, the summary of safety and clinical performance.’;

(z) Section 4.11. is replaced by the following:

‘4.11. *Periodic reviews and extension of a certificate’s period of validity*’

The notified body shall have documented procedures in place relating to periodic reviews of approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates.

Those procedures shall require the manufacturer in question to submit at predefined intervals a summary of changes and of relevant data gathered by the manufacturer’s post-market surveillance system. The notified body shall assess such information and shall pay particular attention to clinical data from post-market surveillance and PMCF activities undertaken since the previous certification or periodic review, including appropriate updates to manufacturers' clinical evaluation reports, without repeating assessments already conducted.

The notified body shall have documented procedures in place relating to the extension of the period of validity of a certificate in cases where it has exceptionally limited the period of validity. Those procedures shall require the manufacturer to submit prior to the expiry of the certificate the data or documentation specified by the notified body to enable it to decide about the extension of the period of validity of the certificate.’;

(6) Annex VIII is amended as follows:

(a) Section 3.2 is replaced by the following:

‘3.2 If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories for a medical device and accessories for a product listed in Annex XVI shall be classified in their own right separately from the device with which they are used.’;

(b) in Section 4.2, first paragraph, the second indent is replaced by the following:

– ‘if they are intended for use for channeling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; by derogation from any other classification rule, blood bags are classified as class IIb.’;

(c) in Section 5.2, the second indent is replaced by the following:

– ‘are reusable surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I;’;

(d) in Section 5.3, the following indent is added:

– ‘are reusable surgical instruments regardless of the body part with which they come into contact, in which case they are classified as class I;’;

(e) Section 5.4 is amended as follows:

(i) the sixth indent is replaced by the following:

– ‘are active implantable devices, in which cases they are classified as class III; ‘;

(ii) the eighth and ninth indents are replaced by the following:

– ‘are total or partial joint replacements, in which case they are classified as class III, with the exception of components such as screws, wedges, plates and instruments and other devices that are well-established technology devices; or

– are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments and other devices that are well-established technology devices.’;

(f) in Section 6.1, the first and second paragraphs are replaced by the following:

‘All active therapeutic devices and all active products listed in Annex XVI intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

All active devices intended to control or monitor the performance of active therapeutic class IIb devices, and of any active product listed in Annex XVI falling in class IIb, or intended directly to influence the performance of such devices are classified as class IIb.’;

(g) Section 6.3 is replaced by the following:

‘6.3 Rule 11

Software which is intended to generate an output that confers a clinical benefit and is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I, unless the output is intended for a disease or condition:

– in a critical situation with a risk of causing death or an irreversible deterioration of a person's state of health, in which case it is classified as class III;

– in a serious situation with a risk of causing a serious deterioration of a person's state of health or a surgical intervention, or to drive clinical management in a critical situation in which cases it is classified as class IIb;

– in a non-serious situation, or to drive clinical management in a serious situation or to inform clinical management in a critical or serious situation in which cases it is classified as class IIa.';

(h) in Section 7.6, the introductory wording is replaced by the following:

'Rule 19

All devices incorporating or consisting of nanomaterial as defined in Commission Recommendation C/2022/3689 are classified as:';

(i) in Section 7.8, the introductory wording is replaced by the following:

'Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed on or in the human body are classified as:';

(7) Annex IX is amended as follows:

(a) in Section 2.3, the third and fourth paragraphs are replaced by the following:

'Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation, as referred to in Annex II and III, as specified in Sections 4.3 to 4.8 for a representative device. However, in case of class IIa devices, Section 3(a) of Annex II shall be excluded from the assessment. In choosing the representative device, the notified body shall apply a risk-based approach, taking into account the principle of proportionality and in particular the physical, chemical, biological characteristics of the device, the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended purpose, the application by the manufacturer of harmonised standards or CS for the device and the results of any previous relevant assessments such as with regard to physical, chemical, biological or clinical properties, that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the representative devices taken.

For class IIa and class IIb devices, the notified body may include a 'for-cause' assessment of the technical documentation of additional representative devices on duly justified grounds identified during the quality management system assessment.

If the quality management system and the technical documentation of the assessed representative device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of its decision to

issue the certificate. The decision shall contain the conclusions of the audit and a reasoned report.';

(b) in Section 3.2, the second indent is replaced by the following:

– 'documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMCF plan, for the representative devices, and of the provisions on vigilance set out in Articles 87 to 92,';

(c) Section 3.3 is replaced by the following:

'3.3 Notified bodies shall periodically carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. On justified grounds, the audit may be conducted remotely instead of on-site. The notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report.

The notified body shall carry out the surveillance audits and assessments once every 12 months. However, where justified in light of the results of previous surveillance audits and assessments, and in the absence of any concerns resulting from data from post-market surveillance or vigilance, the notified body shall carry out the surveillance audits and assessments only once every 24 months.';

(d) Section 3.4 is amended as follows:

(i) the first paragraph is replaced by the following:

'The notified body shall perform short-notice or unannounced audits on the site of the manufacturer and, where appropriate, of the manufacturer's suppliers and/or subcontractors when justified based on concerns related to post-market surveillance or vigilance data or at the request of a competent authority. The short-notice or unannounced audit may be combined with the periodic surveillance assessment referred to in Section 3.3. or be performed in addition to that surveillance assessment.';

(ii) in the second paragraph, the first sentence is replaced by the following:

'Within the context of such unannounced on-site audits, the notified body may test an adequate sample of the devices produced or an adequate sample from the manufacturing process to verify that the manufactured device is in conformity with the technical documentation, with the exception of the devices referred to in the second subparagraph of Article 52(8).';

(iii) in the third paragraph, the first sentence is replaced by the following:

'Instead of, or in addition to, the sampling referred to in the second paragraph, the notified body may take samples of devices from the market to verify that the manufactured device is in conformity with the

technical documentation, with the exception of the devices referred to in the second subparagraph of Article 52(8).';

(e) Section 3.5 is replaced by the following:

'3.5 In the case of class IIa and class IIb devices, and of class III devices that are well-established technology devices, during the surveillance assessment the notified body may include a 'for-cause' assessment of the technical documentation of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds.

In the case of class III devices, with the exception of well-established technology devices, the surveillance assessment shall also include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.';

(f) Section 3.7. is replaced by the following;

'3.7. If the notified body finds a divergence between the sample taken from the devices produced or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose conditions or limitations on it.';

(g) the title of Section 4 is replaced by the following:

'4. Assessment of the technical documentation';

(h) in Section 4.2, the second sentence is replaced by the following:

'It shall include the technical documentation as referred to in Annexes II and III or a plan and related timelines for submission of such technical documentation.';

(i) in Section 4.4, the second sentence is replaced by the following:

'The notified body shall use device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the device in question or the clinical condition in which it is utilised, for the purposes of that review.';

(j) Section 4.8 is replaced by the following:

'The notified body shall provide the manufacturer with a report on the technical documentation assessment, including a clinical evaluation assessment report.';

(k) in Section 4.9, the first and the third sentences are deleted;

(l) Section 5.1 is amended as follows:

(i) the title is replaced by the following:

'5.1 Assessment procedure for devices covered by Article 54';

(ii) in point (a), the first and second paragraphs are replaced by the following:

‘(a) For devices covered by Article 54, the notified body shall, having verified the quality of clinical data supporting the clinical evaluation report of the manufacturer referred to in Article 61(1), prepare a clinical evaluation assessment report which sets out its conclusions concerning the clinical evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication or indications and the PMCF plan referred to in Article 10(3) and Part B of Annex XIV.

The notified body shall transmit its clinical evaluation assessment report, along with the manufacturer's clinical evaluation report and, where applicable, the PMCF plan, to the Commission.’;

(iii) in point (b), the following sentence is added:

‘Where appropriate, the expert panel may also invite the manufacturer to present the conclusions of its clinical evaluation.’;

(iv) point (g) is replaced by the following:

‘(g) The notified body shall give utmost consideration to the views expressed in the scientific opinion of the expert panel and, where appropriate, update its clinical evaluation assessment report. Where the expert panel finds that the level of clinical evidence is not sufficient or otherwise gives rise to serious concerns about the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication(s), and with the PMCF plan, the notified body shall, if necessary, advise the manufacturer to gather additional clinical data and update its clinical evaluation, to limit the intended purpose of the device to certain groups of patients or certain medical indications and/or to impose a limit on the duration of validity of the certificate, to undertake specific PMCF studies, to adapt the instructions for use or the summary of safety and clinical performance, or to impose other conditions in its conformity assessment report, as appropriate. The notified body shall provide an explanation of how it has addressed the views and recommendations expressed in the expert panel opinion and, where it has not followed the views and recommendations of the expert panel, provide a substantiated justification for it. The scientific opinion of the expert panel and the explanation of how is has been addressed or, if applicable, the substantiated justification provided by the notified body shall be publicly available via Eudamed without any confidential information as referred to in Article 109.’;

(m) Section 5.2 is amended as follows:

(i) point (d) is replaced by the following:

‘The medicinal products authority consulted shall provide its opinion to the notified body within 90 days of receipt of all the necessary documentation. This 90-day period may be extended once for a further 30 days on justified grounds. Where the medicinal substance is not previously authorised in the Union, the medicinal products authority

consulted shall provide its opinion within 180 days. When preparing its opinion, the medicinal products authority consulted may request the notified body, or the manufacturer, to provide within a specific time period additional information necessary for its assessment referred to in point (b). In case of such a request, the time-limit set out in this paragraph shall be suspended until the additional information requested is provided.';

(ii) point (g) is replaced by the following:

'(g) Where the medicinal products authority consulted obtains information on the ancillary substance, which could have an impact on the risk or benefit previously established concerning the incorporation of the substance into the device, it shall advise the notified body as to whether this information has an impact on the risk or benefit previously established concerning the incorporation of the substance into the device. In the case of information relating to serious incidents obtained via the notification outlined in the first subparagraph of Article 89(6) of this Regulation, the medicinal products authority consulted shall review the data, which may be presented in aggregated form and may engage with the notified body to obtain further information where necessary. The notified body shall take that advice into account in reconsidering its assessment of the conformity assessment procedure.';

(n) Section 5.3.1. is replaced by the following:

'5.3.1 Substances of human origin or their derivatives

(a) For devices manufactured utilising derivatives of substances of human origin that are covered by this Regulation in accordance with point (g) of Article 1(6) and for devices that incorporate, as an integral part, substances of human origin, or their derivatives, covered by Regulation (EU) 2024/1938, that have an action ancillary to that of the device, the notified body shall, prior to issuing an EU technical documentation assessment certificate, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Regulation (EU) 2024/1938 ('SoHO competent authority') on the aspects relating to donor registration, donor review, collection and testing of the substances of human origin or their derivatives. The notified body shall submit a summary of the preliminary conformity assessment which provides, among other things, information about the non-viability of the substance of human origin in question, donor registration, donor review, collection and testing and the risk or benefit of the incorporation of the substance of human origin or their derivatives into the device.

(b) Within 90 days of receipt of all the necessary documentation, the SoHO competent authority shall provide to the notified body its opinion. This 90-day period may be extended once for a further 30 days on justified grounds.

(c) The scientific opinion of the SoHO competent authority, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion of the SoHO competent authority when making its decision. The notified body shall not deliver the certificate if that scientific opinion is unfavourable. It shall convey its final decision to the SoHO competent authority concerned.

(d) Before any change is made with respect to non-viable substances of human origin or their derivatives incorporated in a device, in particular relating to donor registration, donor review, collection and testing, the manufacturer shall inform the notified body of the intended changes. The notified body shall consult the authority that was involved in the initial consultation, in order to confirm that the quality and safety of the substances of human origin or their derivatives incorporated in the device are maintained. The SoHO competent authority concerned shall take into account the data relating to the usefulness of incorporation of the substances of human origin or their derivatives into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit-risk ratio of the addition of the substances of human origin or their derivatives in the device. It shall provide its opinion within 60 days of receipt of all the necessary documentation regarding the intended changes. The notified body shall not deliver a supplement to the EU technical documentation assessment certificate if the scientific opinion is unfavourable and shall convey its final decision to the SoHO competent authority concerned.

(e) In the case of information relating to serious incidents obtained via the notification outlined in the second subparagraph of Article 89(6), the SoHO competent authority consulted shall review the data and may engage with the notified body to obtain further information where necessary.';

(o) Section 5.3.2. is deleted;

(p) in Section 5.4, points (b), (c) and (d) are deleted;

(8) Annex X is amended as follows:

(a) in Section 3, point (c) is replaced by the following:

'(c) review the clinical evidence presented by the manufacturer in the clinical evaluation report in accordance with Section 4 of Annex XIV. The notified body shall use device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the device in question or to the clinical condition in which it is utilised, for the purposes of that review;';

(b) Section 4 is replaced by the following:

'If the type conforms to this Regulation, the notified body shall issue an EU type-examination certificate. The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body.'

(9) Annex XI is amended as follows:

(a) Section 3 is replaced by the following:

‘3. By way of derogation from Sections 1 and 2, Section 10 or Section 18 of this Annex coupled with the drawing up of technical documentation as set out in Annexes II and III may also be applied by manufacturers of class IIa devices.’;

(b) the following Section 3a is inserted before Part A:

‘3a. By way of derogation from Sections 1 and 2 above, Section 10a may also be applied by manufacturers of class I devices that are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments.’;

(c) in Section 7, the second paragraph is replaced by the following:

‘In the case of class III devices, other than well-established technology devices, surveillance shall also include a check that the quantities of produced or purchased raw material or crucial components approved for the type correspond to the quantities of finished devices.’;

(d) Section 10 is replaced by the following:

’10. Application to class IIa devices

10.1. The manufacturer shall ensure that the quality management system approved for the manufacture of the devices concerned is implemented.

10.2 By virtue of the EU declaration of conformity the manufacturer shall be deemed to ensure and to declare that the class IIa devices in question are manufactured in conformity with the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

10.3. The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include all elements listed in Section 2.1 of Annex IX. The manufacturer shall ensure that an adequate description of all elements listed in Section 2.2, points (a), (b), (d) and (e) of Annex IX is available for the assessment of the quality management system.

10.4 The first four paragraphs of Section 2.3 of Annex IX shall apply.

10.5. Where the assessment under Section 10.4. of this Annex confirms that the devices in question conform to the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them, the notified body shall issue an EU production quality assurance certificate pursuant to Part A of this Annex.

10.6. Section 2.4 of Annex IX shall apply.

10.7. Section 3.1, Section 3.2, first, second and fourth indents, and Sections 3.3 to 3.7 of Annex IX shall apply.

10.8. The manufacturer or its authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

– the EU declaration of conformity,

– the technical documentation referred to in Annexes II and III, and

– the certificate referred to in Section 10.5 of this Annex.

10.9. Section 8 of Annex IX shall apply.';

(e) the following Section 10a is inserted before Part B:

'10a. Application to class I devices that are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments

10a.1. The manufacturer shall ensure that the quality management system approved for the manufacture of the devices concerned is implemented.

10a.2. By virtue of the EU declaration of conformity the manufacturer shall be deemed to ensure and to declare that the devices in question are manufactured in conformity with the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

10a.3. The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include the elements listed in Section 2.1, first to sixth indents, of Annex IX. The manufacturer shall ensure that an adequate description of all elements listed in Section 2.2, points (d) and (e), of Annex IX is available for the assessment of the quality management system.

10a.4. Section 2.3, first and second paragraphs, of Annex IX shall apply. The assessment of the notified body shall be limited:

– in the case of devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions;

– in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements;

– in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

10a.5. Where the assessment under Section 10a.4. confirms that elements of the quality management system comply with the relevant provisions of this Regulation, the notified body shall issue an EU production quality assurance certificate pursuant to this Part of this Annex.

10a.6. Section 2.4 of Annex IX shall apply.

10a.7. Section 3.1, Section 3.2, first, second and fourth indents, Sections 3.3, 3.4 and 3.6 of Annex IX shall apply.

10a.8. The manufacturer or its authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

– the EU declaration of conformity,

– the documentation referred to in the fifth indent of Section 2.1 of Annex IX,

– the certificate referred to in Section 10a.5.

10a.9. Section 8 of Annex IX shall apply.';

(f) in Section 12, the second paragraph is replaced by the following:

'In addition, for devices placed on the market in a sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer shall apply the provisions of Sections 6.1, 6.2, 6.3, first paragraph, 6.4 and 7.';

(g) Section 18 is replaced by the following:

'18. Application to class IIa devices

18.1. Product verification shall be understood to be the procedure whereby after examination of every manufactured device, the manufacturer, by issuing an EU declaration of conformity in accordance with Article 19 and Annex IV, shall be deemed to ensure and to declare that the devices which have been subject to the procedure set out in Sections 14 and 15 conform to the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

18.2. The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which conform to the devices described in the EU declaration of conformity and to the requirements of the Regulation which apply to them. Prior to the start of manufacture, the manufacturer shall prepare documents defining the manufacturing process, in particular as regards sterilisation where necessary, together with all routine, pre-established procedures to be implemented to ensure homogeneous production.

In addition, for devices placed on the market in a sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer shall apply the provisions of Sections 10.3, 10.4, 10.6 and 10.7.

18.3. Sections 13 and 14 shall apply. Section 15 shall apply with the aim of verifying the conformity of the devices with those described in the EU declaration of conformity.

18.4. By way of derogation from Section 17, the manufacturer or its authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

– the EU declaration of conformity,

– the documentation referred to in Section 18.2,

– the technical documentation referred to in Annexes II and III,

– the certificate referred to in Section 15.2.

18.5. Section 8 of Annex IX shall apply.';

(10) Annex XII is amended as follows:

(a) in Chapter I, Section 4, point (b) is replaced by the following:

'(b) EU quality management system certificates and EU quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification and the manufacturing site(s) covered.';

(b) Chapter II is amended as follows:

(i) Section 6 is replaced by the following:

'6. where applicable, date of expiry';

(ii) Section 7 is replaced by the following:

'7. data needed for the unambiguous identification of the device or devices where applicable as specified in Section 4 of Chapter I;';

(iii) Section 10 is replaced by the following:

'10. reference to relevant CS and harmonised standards;';

(11) Annex XIII is amended as follows:

(a) in Section 1, the eighth indent is replaced by the following:

'where applicable, an indication that the device contains or incorporates a medicinal substance, including a human blood or plasma derivative, or tissues or cells of human origin, or of animal origin as referred to in Regulation (EU) No 722/2012, or in any subsequent implementing rules adopted pursuant to this Regulation.';

(b) in Section 5, the first sentence is replaced by the following:

'The manufacturer shall review and document experience gained in the post-production phase, including where applicable from PMCF as referred to in Part B of Annex XIV, and implement appropriate means to apply any necessary corrective action.';

(12) Annex XIV is amended as follows:

(a) Section 1 is amended as follows:

(i) point (a) is amended as follows:

(1) the first indent is replaced by the following:

– 'an identification of the general safety and performance requirements that require support from relevant clinical data, or adequate justification that confirmation of safety and performance based on clinical data is not deemed appropriate in accordance with Article 61(10);';

(2) the seventh and eighth indents are replaced by the following:

– 'an indication how benefit-risk issues relating to specific components such as use of pharmaceutical, non-viable substances of human origin or non-viable animal tissues, are to be addressed;

– where applicable, a clinical development strategy indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF as referred to in Part B with an indication of milestones and a description of potential acceptance criteria;';

(ii) the following paragraph is added:

'Points (b) to (e) shall not apply to devices for which confirmation of safety and performance based on clinical data is not deemed appropriate in accordance with Article 61(10).';

(b) in Section 3, the second and third indents are replaced by the following:

– 'Biological: the device uses the same or similar materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;

– Clinical: the device is used for the same or similar clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.';

(c) in Section 5, the following sentence is inserted after the first sentence:

'Where PMCF is deemed not applicable, the manufacturer shall provide a justification in the post-market surveillance plan as referred to in Section 1 of Annex III.';

(d) Section 7 is replaced by the following:

'7. The manufacturer shall analyse the findings of the PMCF and document the results in the clinical evaluation report and the technical documentation.';

(e) Section 8 is replaced by the following:

'8. The conclusions of the PMCF shall be taken into account for the clinical evaluation referred to in Article 61 and Part A of this Annex and in the risk management referred to in Section 3 of Annex I. If, through the PMCF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.';

(13) Annex XV is amended as follows:

(a) in Chapter I, Section 2.6., the following sentence is added:

'For combined studies, endpoints reporting on the device and medicinal product together may be used.';

(b) Chapter II is amended as follows:

(i) Section 1.4. is replaced by the following:

'1.4. status of the clinical investigation application (i.e. first submission, resubmission, substantial modification);';

(ii) Section 1.6. is replaced by the following:

‘1.6. If the application is a resubmission with regard to a device for which an application has been already submitted, the date or dates and reference number or numbers of the earlier application or, in the case of substantial modification, reference to the original application. The sponsor shall identify all of the changes from the previous application together with a rationale for those changes, in particular, whether any changes have been made to address conclusions of previous competent authority or ethics committee reviews;’.

ANNEX II

Annexes I, II, III, VI, VII, IX, X, XI, XII, XIII and XIV to Regulation (EU) 2017/746 are amended as follows:

(1) Annex I is amended as follows:

(a) Section 16.4. is replaced by the following:

'Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures and cybersecurity, including protection against unauthorised access, necessary to run the software as intended.';

(b) Section 20.1. is amended as follows:

(i) the second sentence of the first paragraph is replaced by the following:

'Such information may appear on the device itself, on the packaging or in the instructions for use, taking into account the following:';

(ii) in point (c), the following sentence is added:

'Labels may be provided in digital form to the extent, and only under the conditions, set out in implementing rules adopted pursuant to this Regulation.';

(iii) point (e) is replaced by the following:

'(e) Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.';

(iv) point (f) is replaced by the following:

'(f) When the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic).';

(v) the following point (k) is added:

'(k) For devices that are used exclusively with a medicinal product in accordance with Article 19 of [Proposal for a Directive on the Union code relating to medicinal products for human use, and repealing Directive 2011/83/EC and Directive 2009/35/EC] and packaged together with a medicinal product, the instructions for use may be included, where needed, as part of the co-packaging of the medicinal product with the device. Moreover, the information on the label of the device may be limited to the particulars referred to in Section 20.2., points (a) and (c), where, following agreement of the competent authority responsible for the authorisation of the medicinal product, the following conditions are met:

(i) the information necessary for safe use and correct functioning of the device is provided to the user with the summary of product characteristics and/or package leaflet of the medicinal product under the responsibility of the marketing authorisation holder set out in [Proposal for a Directive on the Union code relating to medicinal products for human use,

and repealing Directive 2011/83/EC and Directive 2009/35/EC;

(ii) the traceability and identification of the device is ensured by the marketing authorisation holder.';

(c) Section 20.2. is amended as follows:

(i) point (e) is replaced by the following:

'(e) an indication that the device is an *in vitro* diagnostic medical device or an accessory for an *in vitro* diagnostic medical device, or if the device is a 'device for performance study', an indication of that fact;';

(ii) point (j) is replaced by the following:

'(j) where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination thereof, or other terms which accurately reflect the contents of the package;';

(iii) point (r) is replaced by the following:

'(r) where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion thereof;';

(d) Section 20.4.1. is amended as follows:

(i) in point (c), subpoint (viii) is replaced by the following:

'(viii) for companion diagnostics, the International Non-proprietary Name(s) (INN) or description of the specific group of the associated medicinal product(s) for which it is a companion diagnostic.';

(ii) point (d) is replaced by the following:

'(d) an indication that the device is an *in vitro* diagnostic medical device or an accessory for an *in vitro* diagnostic medical device, or, if the device is a 'device for performance study', an indication of that fact;';

(iii) point (h) is replaced by the following:

'(h) a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the critical ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;';

(iv) point (w) is replaced by the following:

'(w) analytical and clinical performance characteristics as referred to in Section 9.1, points (a) and (b) ;';

(v) point (x) is deleted;

(vi) point (z) is replaced by the following:

‘(z) information about the use of available reference measurement procedures and materials by the use;’;

(vii) point (ae) is replaced by the following:

‘(ae) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;’;

(2) Annex II is amended as follows:

(a) Section 1.1. is amended as follows:

(i) point (c) is replaced by the following:

‘(c) the intended purpose of the device as referred to in Section 20.4.1, point (c), of Annex I ;’;

(ii) point (g) is replaced by the following:

‘(g) the description of the components and where appropriate, the description of the critical ingredients of relevant components such as antibodies, antigens, enzymes and nucleic acid primers;’;

(b) in Section 3.1., point (a) is replaced by the following:

‘(a) where applicable, a description of the critical reagents such as antibodies, antigens, enzymes and nucleic acid primers not provided but recommended for use with the device;’;

(c) Section 6.1.2.6., point (c) is replaced by the following:

‘(c) statistical methods such as Receiver Operating Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone.’;

(d) Section 6.1.3. is deleted;

(e) in Section 6.2., the heading and the first paragraph are replaced by the following:

‘6.2. Information on overall performance evaluation and clinical studies

The documentation shall contain the performance evaluation plan referred to in Section 1.1 of Annex XIII and the performance evaluation report referred to in Section 1.3.2 of Annex XIII.’;

(f) in Section 6.5., the following point (e) is added:

‘(e) Where the device incorporates as an integral part a medical device that has an action ancillary to that of the device, as referred to in Article 1(4) of this Regulation, the documentation shall include the results of the assessment of the conformity of the medical device part with the relevant general safety and performance requirements set out in Annex I to Regulation (EU) 2017/745 contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device. Where those results of the conformity assessment are not available and where for the conformity assessment of medical device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, an opinion on the conformity of the medical device part with the relevant general safety and

performance requirements set out in Annex I to Regulation 2017/745 issued by a notified body designated in accordance with that Regulation for the type of device in question shall be included in the documentation.';

(3) Annex III is amended as follows:

(a) in Section 1, point (a), the sixth indent is replaced by the following:

– 'publicly-available information about similar devices.';

(b) Section 2 is replaced by the following:

'2. The PSUR referred to in Article 81 or the post-market surveillance report referred to in Article 80.';

(4) Annex VI is amended as follows:

(a) Parts A and B are replaced by the following:

'PART A

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLE 28

Manufacturers and, where applicable, authorised representatives, and, where applicable, importers shall submit the following information relating to the economic operator:

1. type of economic operator (manufacturer, authorised representative, or importer),
2. name, address and contact details, including the digital contact, of the economic operator,
3. where submission of information is carried out by another person on behalf of any of the economic operators mentioned under Section 1.1, the name, address and contact details, including the digital contact, of that person,
4. name, address and contact details, including the digital contact, of the person or persons responsible for regulatory compliance referred to in Article 15.

PART B

CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 25 AND 26

The manufacturer shall provide to the UDI database the following information relating to the manufacturer and the device:

1. Basic UDI-DI as referred to in Article 24 and any additional UDI-DIs,
2. For devices referred to in Article 110(3), type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body and the link to the information that appears on the certificate and was entered by the notified body in the electronic system on notified bodies and certificates,
3. Member State in which the device is to be or has been placed on the market in the Union,

4. Member States where the device is or is to be made available,
5. presence of substances of human origin or their derivatives (y/n),
6. presence of cells or substances of microbial origin (y/n),
7. risk class of the device,
8. where applicable, the single identification number of the performance study,
9. in the case of devices designed and manufactured by another legal or natural person as referred in Article 10(14), the name, address and contact details, including the digital contact, of that legal or natural person,
10. where applicable, the summary of safety and performance,
11. status of the device (placed on the market, no longer placed on the market, recalled, field safety corrective action initiated),
12. indication as to whether the device is intended for self-testing or near-patient testing.
13. quantity per package configuration,
14. the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number),
15. if applicable, the 'unit of use' UDI-DI (where a UDI is not labelled on the device at the level of its 'unit of use', a 'unit of use' UDI-DI shall be assigned so as to associate the use of a device with a patient),
16. name and address of the manufacturer, as indicated on the label,
17. the SRN issued in accordance with Article 28(2),
18. if applicable, name and address of the authorised representative (as indicated on the label),
19. the medical device nomenclature code as provided for in Article 23,
20. if applicable, name or trade name, and if applicable, additional trade names,
21. if applicable, device model, reference, or catalogue number,
22. additional product description (optional),
23. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),
24. labelled as a single use device (y/n),
25. if applicable, the maximum number of reuses,
26. device labelled sterile (y/n),
27. need for sterilisation before use (y/n),
28. if applicable, the instructions for use, or where available, the URL of the website where the instructions for use are made available,
29. if applicable, critical warnings or contra-indications.';

(b) Part C is amended as follows:

(i) in Section 1, the definition of 'Basic UDI-DI' is replaced by the following:

'**Basic UDI-DI**

The Basic UDI-DI is the primary identifier of a device model. The Basic UDI-DI is the main key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and performance) to connect devices with the same intended purpose, risk class and essential design and manufacturing characteristics. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.';

(ii) Section 4.10. is replaced by the following:

'4.10. Devices that are reusable shall bear a UDI carrier on the device itself. The UDI carrier for reusable devices that require disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device, unless the device is intended to be reused exclusively by or for the same patient. The requirement of this Section shall not apply to devices in the following circumstances:

(a) any type of direct marking would interfere with the safety or performance of the device;

(b) the device cannot be directly marked because it is not technologically feasible.';

(5) Annex VII is amended as follows:

(a) in Section 1.1.1., the following sentence is added:

'It shall also include information about the larger organisation to which the notified body belongs.';

(b) Section 1.1.2. is replaced by the following:

'1.1.2 If the notified body is a legal entity that is part of a larger organisation, the activities of that organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented. In such cases, the requirements set out in Section 1.2 are applicable to both the notified body and the larger organisation to which it belongs. The larger organisation and any of the legal entities belonging to it shall not be involved in the design, manufacture, marketing, installation or maintenance of the devices for which the notified body is designated or offer consultancy services for such activities. They shall not represent the parties engaged in those activities.';

(c) Section 1.1.5. is replaced by the following:

'1.1.5. The notified body shall clearly document its organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel who may have an influence on the

performance by the notified body and on the results of its conformity assessment activities.';

(d) in Section 1.2.9., the following sentence is added:

'The notified body shall have documented procedures in place to offer and carry out dialogues with the manufacturer before and after an application for conformity assessment is lodged.';

(e) Section 1.3.1. is replaced by the following:

'1.3.1. The notified body shall have documented procedures in place ensuring that its personnel, committees, branch offices, subsidiaries, subcontractors, and any associated body or personnel of external bodies respect the confidentiality of the information which comes into its possession during the performance of the conformity assessment activities, except when disclosure is required by law.';

(f) in Section 1.4.2., the second sentence is deleted;

(g) the following Section 1.4.3. is added:

'1.4.3. By way of derogation from Section 1.4.1., the notified body may demonstrate coverage for liability through adherence to a guarantee fund that provides effective protection and is recognised by the Member State(s) concerned.';

(h) Section 1.6.1. is replaced by the following:

'1.6.1. The notified body shall participate in the activities of the notified body coordination group referred to in Article 49 of Regulation (EU) 2017/745 and ensure that its assessment and decision-making personnel are informed of all relevant legislation, standards, guidance and best practice documents adopted in the framework of this Regulation.';

(i) Section 2.1. is replaced by the following:

'2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and is capable of supporting and demonstrating in the most effective manner the consistent fulfilment of the requirements of this Regulation.';

(j) Section 2.3. is replaced by the following:

'2.3. The top-level management of the notified body shall ensure that the quality management system is fully understood, implemented and maintained throughout the notified body organisation including branch offices, subsidiaries and subcontractors involved in conformity assessment activities pursuant to this Regulation.';

(k) Section 3.2.3. is amended as follows:

(i) the first sentence is replaced by the following:

'The personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities shall not be external experts or be subcontracted.';

(ii) in the second sentence, the sixth indent is replaced by the following:

– ‘adequate experience in conformity assessments under this Regulation, Regulation (EU) 2017/745 or previously applicable law within a notified body.’;

(l) in Section 3.2.4., the first sentence is replaced by the following:

‘The notified body shall have permanent availability of personnel with relevant clinical expertise.’;

(m) in Section 3.2.7., the first sentence is replaced by the following:

‘The personnel with overall responsibility for final reviews and decision-making on certification shall not be external experts or be subcontracted.’;

(n) in Section 3.4.1., first paragraph, the following sentence is added:

‘They shall inform the manufacturer accordingly.’;

(o) in Section 4.1., the second paragraph is replaced by the following:

‘The requirements laid down in Sections 4.3., 4.4., 4.7. and 4.8. shall not be subcontracted and shall not be fulfilled by external experts.’;

(p) in Section 4.2., point (a), the second sentence is replaced by the following:

‘That description shall include which languages are acceptable for submission of documentation and for any related correspondence and the modalities for carrying out the dialogue referred to in Section 1.2.9 of this Annex before an application is lodged.’;

(q) in Section 4.3., second paragraph, the third sentence is replaced by the following:

‘This contract shall have clear terms and conditions and contain obligations that enable the notified body to act as required under this Regulation, including an obligation on the manufacturer to inform the notified body of vigilance reports, the right of the notified body to suspend, limit or withdraw certificates issued and the duty of the notified body to fulfil its information obligations.’;

(r) in Section 4.5.1., the second paragraph is amended as follows:

(i) the eighth indent is replaced by the following:

– ‘in the case of class B or class C devices, to assess the technical documentation of the representative device(s),’;

(ii) the tenth indent is deleted;

(iii) the following indents are added:

– where appropriate, to perform a rolling review of the manufacturer’s data or documentation as they become available,

– to leverage evidence from previously performed assessments.’;

(s) Section 4.5.2. is amended as follows:

(i) point (a) is amended as follows:

(1) the introductory wording is replaced by the following:

‘As part of the assessment of the quality management system, a notified body shall prior to or in relation with an audit and in accordance with its documented procedures:’;

(2) the fourth indent is replaced by the following:

– clearly identify, for class B and class C devices, the representative devices selected for the assessment of technical documentation as referred to in Annexes II and II, and';

(ii) in point (b), the fourth indent is replaced by the following:

– 'the documentation shall be sampled in such as a manner as to reflect the risks associated with the intended use of the device, the complexity of the manufacturing technologies, the range and classes of devices produced or under certification and any available post-market surveillance information,';

(t) in Section 4.5.3., the third paragraph which is headed 'Verification by examination and testing of every product batch' is replaced by the following:

'Verification by examination and testing of products or product batches

The notified body shall:

(a) have documented procedures, sufficient expertise and access to facilities for the verification by examination and testing of products or product batches;

(b) establish a test plan identifying all relevant and critical parameters which need to be tested under the notified body's responsibility and document its selection for the selection of the parameters;

(c) have documented procedures to carry out the appropriate assessments and tests in order to verify the conformity of the device with the requirements of this Regulation including, where applicable, procedures in relation to testing by EU reference laboratories in accordance with Annexes IX, X and XI;

(d) have documented procedures providing for the reaching of an agreement with the applicant concerning when and where necessary tests that are not to be carried out by the notified body itself are to be performed;

(e) assume full responsibility for test results in accordance with documented procedures, except where testing was carried out by EU reference laboratories in accordance with Annexes IX, X or XI of this Regulation; test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.';

(u) in Section 4.6., the introductory sentence in the second paragraph is replaced by the following:

'The report(s) of the notified body shall:';

(v) Section 4.8. is amended as follows:

(i) the first sentence is replaced by the following:

'The notified body shall have documented procedures for decision-making including as regards the allocation of responsibilities for the issuance, suspension, limitation and withdrawal of certificates.';

(ii) the third sentence is amended as follows:

(1) the fourth indent is replaced by the following:

– ‘decide whether conditions or limitations need to be defined for the certification,’;

(2) the fifth indent is replaced by the following:

– ‘where appropriate, decide, based on the novelty, risk classification, performance evaluation and conclusions from the risk analysis of the device, on a period of certification,’;

(3) the eighth indent is replaced by the following:

– ‘issue a certificate or certificates in accordance with the minimum requirements laid down in Annex XII and shall indicate whether there are conditions or limitations associated with the certification,’;

(w) Section 4.9. is amended as follows:

(i) in the first paragraph, the fourth indent is replaced by the following:

– ‘the intended purpose of or claims made for the device.’;

(ii) the second paragraph is replaced by the following:

‘The procedures and contractual arrangements referred to in the first paragraph shall clearly distinguish between changes that do not need to be reported, that need to be reported without requiring prior approval and that require prior approval.’;

(iii) the third paragraph is amended as follows:

(1) the introductory sentence is replaced by the following:

‘In accordance with its documented procedures, the notified body in question shall, where changes require prior approval:’;

(2) the following fourth paragraph is added:

‘Where appropriate, the notified body and the manufacturer shall agree on a predetermined change control plan enabling the manufacturer to implement changes in accordance with such a plan without prior information.’;

(x) Section 4.10. is amended as follows:

(i) the first paragraph is amended as follows:

(1) the second indent is replaced by the following:

– ‘for screening relevant sources of scientific and clinical data and post-market information relating to the scope of their designation. That screening shall be conducted in the framework of the coordination group established in Article 49 to avoid unnecessary duplication and to enhance efficiency and work-sharing. The findings from the screening shall be taken into account in the planning and conduct of surveillance activities,’;

(2) the first sentence of the third indent is replaced by the following:

– ‘to assess whether any reported serious incident related to a serious public health threat or any field safety corrective action taken or envisaged by the manufacturer or required of it by a competent authority has an impact on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented.’;

(ii) the second paragraph is amended as follows:

(1) the opening sentence is replaced by the following:

‘The notified body in question shall, with regard to signals arising from vigilance data to which they have access under Article 87(2), decide on which of the following options to apply, where appropriate:’;

(2) the first indent is deleted;

(iii) the third paragraph is amended as follows:

(1) the first indent is replaced by the following:

– ‘conduct surveillance audits of the manufacturer which shall be planned and conducted in line with the relevant requirements in Section 4.5.;

(2) the eight indent is replaced by the following:

– ‘where necessary, impose conditions or limitations on the relevant certificate, or suspend or withdraw it.’;

(y) Section 4.11. is replaced by the following:

‘Periodic reviews and extension of a certificate’s period of validity

The notified body shall have documented procedures in place relating to the periodic reviews of the approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates.

Those procedures shall require the manufacturer in question to submit at predefined intervals a summary of changes and of relevant data gathered by the manufacturer’s post-market surveillance system. The notified body shall assess such information and shall pay particular attention to clinical evidence gained from post-market surveillance and PMPF activities undertaken since the previous certification or periodic review, including appropriate updates to manufacturers' performance evaluation reports, without repeating assessments already conducted.

The notified body shall have documented procedures in place relating to the extension of the period of validity of a certificate in cases where it has exceptionally limited the period of validity. Those procedures shall require the manufacturer to submit prior to the expiry of the certificate the data or documentation specified by the notified body to enable it to decide about the extension of the period of validity of the certificate.’;

(6) Annex IX is amended as follows:

(a) in Section 2.3., the third and fourth paragraphs are replaced by the following:

‘Moreover, in the case of class B and class C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation, as referred to in Annexes II and III, as specified in Sections 4.3. to 4.8., for a representative device selected as follows:

– for class B devices, one device;

– for class C devices, one device per generic device group.

In choosing the representative device, the notified body shall apply a risk-based approach, taking into account the principle of proportionality and in particular, the novelty of the technology, the novelty of the analyte and/or marker being detected, the potential impact on the patient and standard medical practice, similarities in design, technology, manufacturing and, where applicable, sterilisation methods, the intended purpose, the application by the manufacturer of harmonised standards or CS for the device and the results of any previous relevant assessments that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the representative device taken.

The notified body may include a ‘for-cause’ assessment of the technical documentation of additional representative devices on duly justified grounds identified during the quality management system assessment.

If the quality management system and the technical documentation of the assessed representative device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. The decision shall contain the conclusions of the audit and a reasoned report.’;

(b) in Section 3.2., the second indent is replaced by the following:

– ‘the documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMPF plan, for the representative devices, and of the provisions on vigilance set out in Articles 82 to 87,’;

(c) Section 3.3. is replaced by the following:

‘3.3. Notified bodies shall periodically carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. On justified grounds, the audit may be conducted remotely instead of on-site. The notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report.

The notified body shall carry out the surveillance audits and assessments once every 12 months. However, where justified in light of the results of previous surveillance audits and assessments, and in the absence of any concerns resulting from data from post-market surveillance or vigilance,

the notified body shall carry out the surveillance audits and assessments only once every 24 months.';

(d) Section 3.4. is amended as follows:

(i) the first paragraph is replaced by the following:

'3.4. The notified body shall perform audits, at short notice or unannounced, on the site of the manufacturer and, where appropriate, the site of the manufacturer's suppliers and/or subcontractors, when justified based on concerns related to post-market surveillance or vigilance data or at the request of a competent authority. The short-notice or unannounced audit may be combined with the periodic surveillance assessment referred to in Section 3.3. or be performed in addition to that surveillance assessment.';

(ii) in the second paragraph, the first sentence is replaced by the following:

'Within the context of such unannounced on-site audits, the notified body may test an adequate sample of the devices produced or an adequate sample from the manufacturing process to verify that the manufactured device is in conformity with the technical documentation.';

(iii) in the third paragraph, the first sentence is replaced by the following:

'Instead of, or in addition to, the sampling referred to in the second paragraph, the notified body may take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation.';

(e) Section 3.5. is replaced by the following:

'3.5. In the case of class B and class C devices, during the surveillance assessment the notified body may include a 'for-cause' assessment of the technical documentation of representative devices where the notified body has identified potential concerns on the basis of post-market surveillance data or other duly justified grounds.';

(f) Section 3.7. is replaced by the following:

'3.7. If the notified body finds a divergence between the sample taken from the devices produced or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose conditions or limitations on it.';

(g) the heading of Section 4 is replaced by the following:

'**4. Assessment of the technical documentation'**;

(h) in Section 4.2., the second sentence is replaced by the following:

'It shall include the technical documentation as referred to in Annexes II and III or a plan for submission of such technical documentation.';

(i) in Section 4.4., the second sentence is replaced by the following:

'The notified body shall use device reviewers with sufficient clinical expertise and including external clinical experts with direct and current experience

relating to the clinical application of the device in question for the purposes of that review.';

(j) Section 4.8. is replaced by the following:

'4.8. The notified body shall provide the manufacturer with a report on the technical documentation assessment, including a performance evaluation assessment report.';

(k) Section 4.9. is amended as follows:

(i) the second paragraph is deleted;

(ii) the fourth paragraph is replaced by the following:

'The scientific opinion of the EU reference laboratory and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall, when making its decision, give due consideration to the views expressed in the scientific opinion of the EU reference laboratory. The notified body shall not deliver the certificate if the scientific opinion of the EU reference laboratory is unfavourable.';

(l) in Section 4.10., the first and third sentences are deleted;

(m) Section 4.12. is amended as follows:

(i) the third sentence is replaced by the following:

'Furthermore, the manufacturer shall make the samples of manufactured batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the manufacturer shall send samples of the manufactured batches of devices to the EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate tests.';

(ii) the following sentence is added:

'Where no EU reference laboratory has been designated in accordance with Article 100, those arrangements may include that the notified body conducts verification of samples or batches by alternative means.';

(n) Section 5.1. is amended as follows:

(i) the heading is replaced by the following:

'Assessment of the technical documentation of class B, C and D devices for self-testing';

(ii) point (a) is replaced by the following:

'(a) The manufacturer of class B, C and D devices for self-testing shall lodge with the notified body an application for the assessment of the technical documentation.';

(iii) point (b)(iii) is replaced by the following:

'(iii) data showing the suitability of the device in view of its intended purpose for self-testing;';

(o) Section 5.2. is amended as follows:

(i) point (c) is replaced by the following:

‘(c) The notified body shall, before issuing an EU technical documentation assessment certificate for the companion diagnostic and on the basis of the draft summary of safety and performance and the draft instructions for use, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, either of which to be referred to in this Section as ‘the medicinal products authority consulted’ depending on which has been consulted under this point, regarding the suitability of the clinical performance of the device in relation to the medicinal product concerned. The assessment of the medicinal products authority consulted shall not repeat the assessment to be performed by the notified body in accordance with this Regulation. Where the medicinal product falls exclusively within the scope of the Annex I to Regulation (EC) No 726/2004 of the European Parliament and of the Council*, the notified body shall seek the opinion of the EMA. If the medicinal product concerned is already authorised, or if an application for its authorisation has been submitted, the notified body shall consult the medicinal products authority, or the EMA, that is responsible for the authorisation.

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* Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/726/oj).’;

(ii) in point (d), after the second sentence the following sentences are inserted:

‘When preparing its opinion, the medicinal products authority consulted may request the notified body, or the manufacturer, to provide within a specific time period additional information necessary for its assessment referred to in point (c). In case of such a request, the time-limit set out in this paragraph shall be suspended until the additional information requested is provided.’;

(iii) in point (f), the first sentence is replaced by the following:

‘Before changes affecting the performance and/or the intended purpose and/or the suitability of the clinical performance of the device in relation to the medicinal product concerned are made, the manufacturer shall inform the notified body of the changes.’;

(iv) the following point (g) is added:

‘(g) points (c) to (f) shall not apply where the following conditions are met:

(i) the companion diagnostic has the same intended purpose as another already CE-marked companion diagnostic for which

a medicinal products authority issued a favourable opinion in accordance with point (d) or Section 3 of Annex X, point (k)

(ii) the manufacturer shows equivalent performance to that already CE-marked companion diagnostic.';

(7) Annex X is amended as follows:

(a) Section 2 is amended as follows:

(i) the third indent is replaced by the following:

– 'in the case of devices for self-testing, test reports, including results of studies carried out with intended users, and data showing the handling suitability of the device in relation to its intended purpose for self-testing';

(ii) the fifth indent is replaced by the following:

– 'data showing the suitability of the device in relation to its intended purpose for self-testing,';

(b) Section 3 is amended as follows:

(i) point (c) is replaced by the following

'(c) review the clinical evidence presented by the manufacturer in the performance evaluation report in accordance with Section 1.3.2 of Annex XIII. The notified body shall use device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the clinical application of the device in question for the purposes of that review;';

(ii) point (i) is replaced by the following:

'(i) draw up an EU type-examination report on the results of the assessments and tests carried out under points (a) to (g), including the performance evaluation assessment report referred to in point (e);';

(iii) point (j) is amended as follows:

(1) the second paragraph is deleted;

(2) the fourth paragraph is replaced by the following:

'The scientific opinion of the EU reference laboratory and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion of the EU reference laboratory, when making its decision. The notified body shall not deliver the certificate if the scientific opinion of the EU reference laboratory is unfavourable;';

(iv) point (k) is replaced by the following:

'(k) for companion diagnostics, seek the opinion, on the basis of the draft summary of safety and performance and the draft instructions for use, of one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the

EMA (either of which to be hereinafter referred to as 'the medicinal products authority consulted' depending on which has been consulted under this point) on the suitability of the clinical performance of the device in relation to the medicinal product concerned. The assessment of the medicinal products authority consulted shall not repeat the assessment to be performed by the notified body in accordance with this Regulation. Where the medicinal product falls exclusively within the scope of the Annex I of Regulation (EC) No 726/2004, the notified body shall consult the EMA. If the medicinal product concerned is already authorised, or if an application for its authorisation has been submitted, the notified body shall consult the medicinal products competent authority, or the EMA, that is responsible for the authorisation. The medicinal products authority consulted shall deliver its opinion within 60 days of receipt of all the necessary documentation. This 60-day period may be extended once for a further 60 days on justified grounds. When preparing its opinion, the medicinal products authority consulted may request the notified body, or the manufacturer, to provide within a specific time period additional information necessary for its assessment. In case of such a request, the time-limit set out in this paragraph shall be suspended until the additional information requested is provided. The opinion of the medicinal products authority consulted and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the opinion expressed by the medicinal products authority consulted when making its decision. It shall convey its final decision to the medicinal products authority consulted.

This point shall not apply where the following conditions are met:

(i) the companion diagnostic has the same intended purpose as another already CE-marked companion diagnostic for which a medicinal products authority issued a favourable opinion in accordance with the previous paragraph or Section 5.2. of Annex IX, point (d);

(ii) the manufacturer shows equivalent performance to that already CE-marked companion diagnostic; and'

(v) point (l) is replaced by the following:

'(l) draw up the EU type-examination report referred to in point (i) taking into account the scientific opinions provided under points (j) and (k),'

(c) in Section 4, the second sentence is deleted;

(d) in Section 5.5., the first sentence is replaced by the following:

'Where the changes affect the performance or the intended purpose of a companion diagnostic approved through the EU type-examination certificate or the suitability of its clinical performance in relation to a medicinal product, the notified body shall consult the medicinal products competent authority that was involved in the initial consultation or the EMA.';

(8) Annex XI is amended as follows:

(a) in Section 2, the second sentence is replaced by the following:

'By issuing an EU declaration of conformity, the manufacturer shall be deemed to ensure, and to declare, that the device concerned meets the requirements of this Regulation which apply to the device, and in the case of devices that undergo a type examination, conforms to the type described in the EU type-examination certificate.';

(b) Section 5.1. is amended as follows:

(i) the third sentence is replaced by the following:

'Furthermore, the manufacturer shall make samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the manufacturer shall send samples of the manufactured devices or batches of devices to an EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate laboratory tests.';

(ii) the following sentence is added:

'Where no EU reference laboratory has been designated in accordance with Article 100, those arrangements may include that the notified body conducts verification of samples or batches by alternative means.';

(9) Annex XII is amended as follows:

(a) Chapter I is amended as follows:

(i) in Section 4, point (b) is replaced by the following:

'(b) EU quality management system certificates and EU production quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification, and the manufacturing site(s) covered.';

(ii) Section 7 is deleted;

(b) Chapter II is amended as follows:

(i) Section 6 is replaced by the following:

'6. where applicable, date of expiry;';

(ii) Section 7is replaced by the following

'7. data needed for the unambiguous identification of the device or devices where applicable as specified in Section 4 of Chapter I;';

(iii) Section 10 is replaced by the following:

'10. reference to relevant CS and, harmonised standards;';

(10) Annex XIII is amended as follows:

(a) Section 1.1. is amended as follows:

(i) the first and second indents are replaced by the following:

– ‘a specification of the intended purpose of the device as referred to in Section 20.4.1, point (c), of Annex I, including a specification of the analyte or marker to be determined by the device;

– ‘a specification of the characteristics of the device as described in Section 9 of Annex I;’;

(ii) the third indent is deleted;

(b) in Section 1.2., the third indent is replaced by the following:

– ‘generate any new or additional data necessary to address outstanding issues; where appropriate this may be supported by computational modelling and in silico testing.’;

(c) in Section 1.2.1., the second paragraph is replaced by the following:

‘The scientific validity of the analyte or marker shall be demonstrated and documented in a dedicated section of the performance evaluation report.’;

(d) in Section 1.2.2., the fourth paragraph is replaced by the following:

‘Analytical performance shall be demonstrated and documented in a dedicated section of the performance evaluation report.’;

(e) Section 1.2.3. is replaced by the following:

‘1.2.3. Demonstration of the clinical performance

The manufacturer shall demonstrate the clinical performance of the device in relation to all the parameters described in point (b) of Section 9.1. of Annex I, unless any omission can be justified as not applicable.

Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources:

– clinical performance studies of the device concerned or of a device for which equivalence to the device concerned can be demonstrated;

– other studies published in scientific literature on the device concerned or of a device for which equivalence to the device concerned can be demonstrated;

– other clinical experience published in peer-reviewed scientific literature with the device concerned or a device for which equivalence to the device concerned can be demonstrated;

– clinically relevant information coming from post-market surveillance, in particular the PMPF;

– published experience gained by routine diagnostic testing.

Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data.

Clinical performance shall be demonstrated and documented in a dedicated section of the performance evaluation report.’;

(f) in Section 1.3.1., the first sentence is replaced by the following:

‘The manufacturer shall assess all relevant scientific validity, analytical and clinical performance data.’;

(g) in Section 1.3.2., first paragraph, the second sentence is replaced by the following:

'This report shall include an assessment of scientific validity, analytical performance and clinical performance allowing demonstration of sufficient clinical evidence.';

(h) Section 1.3.3. is deleted;

(i) Section 2.3.2., second paragraph, is amended as follows:

(i) in point (k), the reference to 'Section 9.1 of Chapter I of Annex I' is replaced by the reference to 'Section 9.1 of Annex I';

(ii) in point (l), the following sentence is added:

'for combined studies, endpoints reporting on the device and medicinal product together may be used;';

(iii) point (n) is replaced by the following:

'information on use of data from left-over specimen banks, genetic or tissue banks, patient or disease registries etc. with description of reliability and representativity and statistical analysis approach; assurance of relevant method for determining the true clinical status of patient specimens;';

(j) Section 3, is replaced by the following:

'3. OTHER PERFORMANCE STUDIES

By analogy, the performance study plan referred to in Section 2.3.2, and the performance study report, referred to in Section 2.3.3, shall be documented for performance studies other than clinical performance studies.';

(k) in Section 4, first paragraph, the following sentence is added:

'Where PMCF is deemed not applicable, the manufacturer shall provide a justification in the post-market surveillance plan as referred to in Section 1 of Annex III.';

(l) Section 6 is replaced by the following:

'6. The manufacturer shall analyse the findings of the PMPF and document the results in the performance evaluation report and the technical documentation.';

(m) Section 8 is deleted;

(11) Annex XIV is amended as follows:

(a) Chapter I is amended as follows:

(i) Section 1.2. is replaced by the following:

'1.2. if different from those in Section 1.1, name, address and contact details of the manufacturer of the device intended for the performance study and, if applicable, of its authorised representative;';

(ii) Section 1.5. is replaced by the following

‘1.5. status of the performance study, such as the first submission, resubmission, substantial modification;’;

(iii) Section 1.7. is replaced by the following:

‘1.7. if the application is a resubmission with regard to a device for which an application has been already submitted, the date or dates and reference number or numbers of the earlier application or in the case of substantial modification, reference to the original application.’.