



Council of the  
European Union

Brussels, 21 September 2015  
(OR. en)

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**Interinstitutional File:**  
**2012/0266 (COD)**

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12040/1/15  
REV 1

PHARM 36  
SAN 281  
MI 567  
COMPET 410  
CODEC 1193

**NOTE**

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From: General Secretariat of the Council  
To: Permanent Representatives Committee/Council

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No. prev. doc.: 9769/15 PHARM 26 SAN 176 MI 391 COMPET 304 CODEC 858 + ADD 1  
No. Cion doc.: 14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 +  
COR 1

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Subject: Proposal for a Regulation of the European Parliament and of the Council  
on **medical devices**, and amending Directive 2001/83/EC, Regulation  
(EC) No 178/2002 and Regulation (EC) No 1223/2009

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Delegations will find in the Annex to this document the consolidated text of the recitals and articles of the proposed Regulation on medical devices prepared by the Luxembourg Presidency with a view to the finalisation of a General Approach, thus completing the partial General Approach reached at the meeting of the Council (EPSCO) on 19 June 2015.

New text compared to the Commission proposal is written in *bold italics*. Deletions are marked by ~~strikethrough~~.

**Technical comments are given on next page.**

The text in this document was presented to delegations in documents WK 75/2015 for the recitals, and WK 57/2015 as amended by WK 64/2015 REV 1 for the articles.

**The content of this revised version is the same as of the original document, but:**

- 1) the revised document is public;**
  - 2) the revised document is directed to the Permanent Representatives Committee and to the Council;**
  - 3) a number of formatting errors are removed.**
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Proposal for a  
**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and**  
**Regulation (EC) No 1223/2009**  
(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)(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<sup>1</sup>,  
~~Having regard to the opinion of~~ **After consulting** the Committee of the Regions<sup>2</sup>,  
~~After consulting the European Data Protection Supervisor,~~<sup>3</sup>  
Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices<sup>4</sup> and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices<sup>5</sup> constitute the Union regulatory framework for medical devices, other than *in vitro* diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.

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<sup>1</sup> OJ C [...], [...], p. [...].

<sup>2</sup> ~~OJ C [...], [...], p. [...].~~ The Committee of the Regions decided to refrain from giving an opinion.

<sup>3</sup> ~~OJ C [...], [...], p. [...].~~ Replaced by Recital (70a).

<sup>4</sup> OJ L 189, 20.7.1990, p. 17.

<sup>5</sup> OJ L 169, 12.7.1993, p. 1.

- (2) This Regulation aims to ensure the *smooth* functioning of the internal market as regards medical devices, taking as a base a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for medical devices to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 TFEU, this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for those medical devices by ensuring, among other things, that data generated in clinical investigations is reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.
- (3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding devices should be introduced, to improve health and safety.
- (4) To the extent possible, guidance developed for medical devices at international level, in particular in the context of the Global Harmonization Task Force (GHTF) and its follow-up initiative the International Medical Devices Regulators Forum, should be taken into account to promote the global convergence of regulations which contributes to a high level of safety protection worldwide and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification criteria, conformity assessment procedures and clinical investigations.
- (5) For historic reasons active implantable medical devices, covered by Directive 90/385/EEC, and other medical devices, covered by Directive 93/42/EEC, were regulated in two separate legal instruments. In the interest of simplification, both directives, which have been amended several times, should be replaced by a single legislative act applicable to all medical devices other than *in vitro* diagnostic medical devices.

- (6) ~~A Regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for divergent transposition by Member States. Moreover, a Regulation ensures that legal requirements are implemented at the same time throughout the Union.~~
- (7) The scope of application of this Regulation should be clearly delimited from other Union harmonisation legislation concerning products, such as *in vitro* diagnostic medical devices, medicinal products, cosmetics and food. Therefore, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>6</sup> should be amended to exclude medical devices from its scope.
- (8) It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. If necessary, the Commission may decide *on its own initiative*, on a case-by-case basis, whether or not a product falls within the definition of a medical device or of an accessory to a medical device. ***Such action should also be taken at a duly substantiated request of a Member State.***
- (8a) Since in some cases it is difficult to distinguish between medical devices and cosmetic products, the possibility to take an EU-wide decision regarding the regulatory status of a product should also be introduced in Regulation No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products<sup>7</sup>.

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<sup>6</sup> OJ L 31, 1.2.2002, p.1.

<sup>7</sup> OJ L 342, 22.12.2009, p. 59.

- (9) Products which combine a medicinal product or substance and a medical device, are regulated either under this Regulation or under Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use<sup>8</sup>. It should be ensured that appropriate interaction exists between the two legislative acts in terms of consultations during the pre-market assessment and exchange of information on vigilance cases occurring with combination products. For medicinal products that integrate a medical device part, compliance with the general safety and performance requirements of the device part should be adequately assessed in the context of the marketing authorisation. Directive 2001/83/EC should therefore be amended.

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<sup>8</sup> OJ L 311, 28.11.2001, p. 67.

(10) Union legislation, *in particular Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004<sup>9</sup> and Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells<sup>10</sup>*, is incomplete in respect of certain products manufactured utilising ~~non-viable human derivatives of~~ tissues or cells *of human origin* that *are non-viable or are rendered non-viable*. ~~have undergone substantial manipulation and that are not covered by Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004<sup>11</sup>. Whilst donation, procurement and testing of the human tissues and cells used for the manufacture of those products should remain within the scope of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells<sup>12</sup>, the *Such* finished products *utilising those derivatives* should come under the scope of this Regulation, *provided they comply with the definition of a medical device, or are covered by this Regulation*. ~~Human tissues and cells that are not substantially manipulated, such as human demineralised bone matrix, and products derived from such tissues and cells, should not be covered by this Regulation.~~~~

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<sup>9</sup> OJ L 324, 10.12.2007, p. 121.

<sup>10</sup> OJ L 102, 7.4.2004, p. 48.

<sup>11</sup> OJ L 324, 10.12.2007, p. 121.

<sup>12</sup> OJ L 102, 7.4.2004, p. 48.

- (11) Certain ~~implantable and other invasive~~ **groups of** products for which the manufacturer claims only an aesthetic or another non-medical purpose but which are similar to medical devices in terms of functioning and risks profile should be covered by this Regulation. ***In order for manufacturers to be able to demonstrate conformity of such products, the Commission should adopt common specifications at least on application of risk management and of general safety and performance requirements and clinical investigations and clinical evaluation applicable to those products. These common specifications should be developed specifically for a group of products without a medical purpose and should not be used for conformity assessment of the analogous devices with a medical purpose.***
- (12) Like for products that contain viable tissues or cells of human or animal origin, that are explicitly excluded from Directives 90/385/EEC and 93/42/EEC and hence from this Regulation, it should be clarified that products ~~that contain living~~ **utilising viable** biological substances of other origin ***in order to achieve or support the intended purpose of the product*** are also not covered by this Regulation.
- (13) There is scientific uncertainty about the risks and benefits of nanomaterials used for medical devices. In order to ensure a high level of health protection, free movement of goods and legal certainty for manufacturers, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial<sup>13</sup>, with the necessary flexibility to adapt this definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of medical devices, the manufacturers should take special care when using nanoparticles that can be released to the human body and those devices should be subject to the most severe conformity assessment procedure.

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<sup>13</sup> OJ L 275, 20.10.2011, p. 38.



- (14) Aspects addressed by Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC<sup>14</sup> and aspects addressed by Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC<sup>15</sup> are an integral part of the general safety and performance requirements for medical devices. Consequently, this Regulation should be considered a *lex specialis* in relation to ~~this~~ *that* Directives.
- (15) This Regulation should include requirements regarding the design and manufacture of medical devices emitting ionizing radiation without affecting the application of Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom<sup>16</sup> 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation<sup>17</sup> nor of Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure and repealing Directive 84/466/Euratom<sup>18</sup> which pursues other objectives.
- (16) It should be made clear that the requirements of this Regulation also apply to the countries that have entered into international agreements with the Union which confer on that country the same status as a Member State for the purpose of application of this Regulation, as it is currently the case with the Agreement on the European Economic Area<sup>19</sup>, the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment and the Agreement of 12 September 1963 establishing an association between the European Economic Community and Turkey<sup>20</sup>.

<sup>14</sup> OJ L 390, 31.12.2004, p. 24

<sup>15</sup> OJ L 157, 9.6.2006, p. 24.

<sup>16</sup> *OJ L 13, 17.1.2014, p. 1.*

<sup>17</sup> OJ L 159, 29.6.1996, p. 1.

<sup>18</sup> OJ L 180, 9.7.1997, p. 22.

<sup>19</sup> OJ L 1, 3.1.1994, p. 3.

<sup>20</sup> OJ 217, 29.12.1964, p. 3687.

- (17) It should be made clear that medical devices offered to persons in the Union by means of information society services within the meaning of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations<sup>21</sup> as well as devices used in the context of a commercial activity to provide a diagnostic or therapeutic service to persons within the Union must comply with the requirements of this Regulation ~~at the latest~~ when the product is placed on the market or the service is provided in the Union.
- ~~(18) It is appropriate to adapt the general safety and performance requirements to technical and scientific progress, for example for software that is specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device.~~
- (18a) It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is qualified as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for well-being application is not a medical device. The qualification of software, either as device or accessory, is independent of its location or type of interconnection between the software and a device.*
- (19) To recognise the important role of standardisation in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No [.../...] on European standardisation<sup>22</sup> should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as quality and risk management.

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<sup>21</sup> OJ L 204, 21.7.1998, p. 37, as amended by Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998, OJ L 217, 5.8.1998, p. 18.

<sup>22</sup> OJ L [...], [...], p. [...].

- (20) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices<sup>23</sup> allows the Commission to adopt common technical specifications for specific categories of *in vitro* diagnostic medical devices. In areas where no harmonised standards exist or where they are not sufficient, the Commission should be empowered to lay down ~~technical~~ specifications which provide a means to comply with general safety and performance requirements and requirements for clinical **investigations and clinical** evaluation and/or post-market clinical follow-up.
- (21) The definitions in the field of medical devices, ~~for example~~ regarding **the device itself, the making available of devices**, economic operators, **users and specific processes, the conformity assessment**, clinical investigations **and clinical evaluations**, ~~and~~ vigilance **and market surveillance, standards and other technical specifications**, should be aligned with well-established practice at Union and international level in order to enhance legal certainty.
- (22) The rules applicable to medical devices should be aligned, where appropriate, with the New Legislative Framework for the Marketing of Products, which consists of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93<sup>24</sup> and Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC<sup>25</sup>.
- (23) The rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to medical devices and their accessories covered by this Regulation which does not prevent Member States from choosing the competent authorities to carry out those tasks.

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<sup>23</sup> OJ L 331, 7.12.1998, p. 1.

<sup>24</sup> OJ L 218, 13.8.2008, p. 30.

<sup>25</sup> OJ L 218, 13.8.2008, p. 82.

- (24) It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors, **building on** ~~as laid down in~~ the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the different parts of this Regulation, to enhance understanding of the legal requirements and thus to improve regulatory compliance by the relevant operators.
- (24a) For the purpose of this Regulation the activities of distributors include acquisition, holding, and supplying of medical devices.**
- (25) Several of the obligations on manufacturers, such as clinical evaluation or vigilance reporting, that were set out only in the annexes of Directives 90/385/EEC and 93/42/EEC should be incorporated into the enacting provisions of this Regulation to ~~enhance legal certainty~~ **facilitate its application.**
- (26) To ensure that medical devices manufactured in series production continue to be in conformity with the requirements of this Regulation and that experience from the use of their medical devices is taken into account for the production process, all manufacturers should have a quality management system and a post-market surveillance ~~plan~~ **system** in place which should be proportionate to the risk class and the type of the medical device. **In addition, in order to minimize risks or prevent incidents related to medical devices, manufacturers should establish a system for risk management and a system for reporting of incidents and field safety corrective actions.**
- (27) It should be ensured that supervision and control of the manufacture of **and the post-market surveillance and vigilance activities of** medical devices ~~is~~ **are** carried out within the manufacturer's organisation by a person **responsible for regulatory compliance** who fulfils minimum conditions of qualification.

(28) For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the medical devices produced by those manufacturers and in serving as their contact person established in the Union. The tasks of an authorised representative should be defined in a written mandate ~~with the manufacturer which for example may allow the authorised representative to lodge an application for a conformity assessment procedure, to report events under the vigilance system or to register devices placed on the Union market. The mandate should empower the authorised representative to~~ duly fulfil certain defined tasks. Considering the role of authorised representatives, the minimum requirements to be met by them should be clearly defined, including the requirement of having available a person who fulfils minimum conditions of qualification which should be similar to those for a manufacturer's ~~qualified~~ person ***responsible for regulatory compliance*** ~~but, with a view to the authorised representative's tasks, could also be satisfied by a person with qualification in law.~~

***(28a) Where, in the course of a clinical investigations, damage caused to the subject leads to the civil or criminal liability of the investigator or the sponsor, the conditions for liability in such cases, including issues of causality and the level of damages and sanctions, should remain governed by national law.***

(29) To ensure legal certainty in respect of the obligations incumbent on economic operators, it is necessary to clarify when a distributor, importer or other person is to be considered the manufacturer of a medical device.

(30) Parallel trade in products already placed on the market is a lawful form of trade within the internal market on the basis of Article 34 TFEU subject to the limitations set by the protection of health and safety and by the protection of intellectual property rights provided by Article 36 TFEU. Application of this principle is, however, subject to different interpretations in the Member States. The conditions, in particular the requirements for relabelling and repackaging, should therefore be specified in this Regulation, taking into account the case-law of the European Court of Justice<sup>26</sup> in other relevant sectors and existing good practices in the field of medical devices.

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<sup>26</sup> Judgment of the Court of 28 July 2011 in joined cases C-400/09 and C-207/10.

- (31) The findings of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), established by Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC<sup>27</sup>, in its scientific opinion of 15 April 2010 on the safety of reprocessed medical devices marketed for single-use, and of the Commission in its report of 27 August 2010 to the European Parliament and the Council on the issue of reprocessing of medical devices in the European Union, in accordance with Article 12a of Directive 93/42/EEC<sup>28</sup>, call for regulation of the reprocessing of single-use devices in order to ensure a high level of protection of health and safety whilst allowing this practice to further develop under clear conditions. ***The reprocessing and further use of single-use devices (SUDs) may only take place where permitted by national law, and in respect of the requirements laid down in this Regulation.*** By reprocessing a single-use device its intended purpose is modified and ***with the view to make it suitable for further use within the Union*** the reprocessor should therefore be considered the manufacturer of the reprocessed device. ***By way of derogation, Member States may decide that the reprocessing and re-use of SUDs within a health institution may vary from the obligations of the manufacturer described in this Regulation. In principle this is only permitted when adequate common specifications are in place and if appropriate national regulations exist and are applied in the reprocessing of these devices which ensure at least the same level of security as in case of the corresponding initial SUDs. This also applies if the reprocessing is carried out by an external reprocessor on behalf of a health institution.***
- (32) Patients who are implanted with a device should be given essential information related to the implanted device allowing it to be identified and containing any necessary warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.

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<sup>27</sup> OJ L 241, 10.9.2008, p. 21.

<sup>28</sup> COM(2010)443 final.

- (33) Medical devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to their placing on the market or putting into service for reasons related to the requirements laid down in this Regulation.
- (34) The traceability of medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve purchase-policy and stock-management by ~~hospitals~~ **health institutions**.
- (34a) The UDI system should apply to all medical devices placed on the market except custom-made devices and be based on internationally recognised principles including definitions that are compatible with those used by major trade partners. In order for the European Unique Device Identification System to become functional in time for the application of this regulation detailed rules should be laid down in this Regulation.*
- (35) Transparency and better information are essential **in the public interest, to protect public health**, to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.
- (35a) To facilitate the functioning of the European Databank on medical devices (Eudamed), a medical device nomenclature should be available free of charge to manufacturers and other natural or legal persons obliged to use that nomenclature under this Regulation. Furthermore this nomenclature should be provided, to the maximum possible extent free of charge, also to other stakeholders.*

- (36) One key aspect is the creation of a central database that should integrate different electronic systems, ~~with the UDI as an integral part of it~~, to collate and process information regarding medical devices on the market and the relevant economic operators, ***certain aspects of conformity assessment, notified bodies***, certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) set up by Commission Decision [2010/227/EU](#) of 19 April 2010 on the European Databank for Medical Devices<sup>29</sup>.
- (37) Eudamed's electronic systems regarding devices on the market, the relevant economic operators and certificates should enable the public to be adequately informed about devices on the Union market. The electronic system on clinical investigations should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and, ~~in this case~~, to report serious adverse events, ***device deficiencies and related updates***. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by ~~national~~ competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

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<sup>29</sup> OJ L 102, 23.4.2010, p. 45.



- (38) In respect of data collated and processed through the electronic systems of Eudamed, Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>30</sup> applies to the processing of personal data carried out in the Member States, under the supervision of the Member States competent authorities, in particular the public independent authorities designated by the Member States. Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data<sup>31</sup> applies to the processing of personal data carried out by the Commission within the framework of this Regulation, under the supervision of the European Data Protection Supervisor. In accordance with Article 2(d) of Regulation (EC) No 45/2001, the Commission should be designated as the controller of Eudamed and its electronic systems.
- (39) For ~~high-risk~~ **class III** medical devices **and implantable devices**, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the clinical evaluation in a document that should be publicly available.
- (39a) The summary of safety and clinical performance should include in particular the place of the device in the context of diagnostic or therapeutic options taking into account the clinical evaluation of the device when compared to the other diagnostic or therapeutic alternates and the specific conditions under which this device and its alternatives may be considered.*
- (40) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.

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<sup>30</sup> OJ L 281, 23.11.1995, p. 31.

<sup>31</sup> OJ L 8, 12.1.2001, p. 1.

- (40a) The outcome of the Notified Body's assessment of the manufacturer's technical documentation and clinical evaluation documentation should be critically evaluated by the national authority responsible for notified bodies and sampled as part of the risk based approach to the oversight and monitoring activities of the notified body.***
- (41) The position of notified bodies vis-à-vis manufacturers should be strengthened, including their right and duty to carry out unannounced ~~factory~~ ***on-site inspections audits*** and to conduct physical or laboratory tests on medical devices to ensure continuous compliance by manufacturers after receipt of the original certification.
- (41a) To increase transparency on the oversight of notified bodies by national authorities, the responsible authorities should publish information on their provisions on the assessment, designation and monitoring of notified bodies for medical devices. In accordance with good administrative practice this information should be kept up to date by the national authority in particular to reflect relevant, significant or substantive changes to the procedures.***
- (41b) In particular in view of the responsibility of Member States for the organisation and delivery of health services and medical care, Member States may lay down additional requirements on notified bodies designated for conformity assessment of devices based on their territory as concerns issues that are not regulated in this Regulation. That possibility is without prejudice to more specific horizontal EU legislation on notified bodies and equal treatment of notified bodies.***

(42) For ~~high risk~~ **class III implantable** medical devices, authorities should be informed ~~at an early stage~~ about devices which are subject to conformity assessment and **experts panels should be given the right requested**, ~~on scientifically valid grounds~~, to scrutinise the preliminary assessment conducted by notified bodies **on clinical data**, ~~in particular regarding novel devices, devices for which a novel technology is being used, devices belonging to a category of devices with increased serious incident rates, or devices for which significant discrepancies in the conformity assessments by different notified bodies have been identified in respect of substantially similar devices.~~ **This clinical evaluation consultation should lead to a harmonised evaluation on high risk medical devices by sharing expertise on clinical aspects and elaborating common specifications on categories of devices that have undergone this consultation process.** ~~The process foreseen in this Regulation does not prevent a manufacturer from informing voluntarily a competent authority of his intention to file an application for conformity assessment for a high risk medical device before submitting the application to the notified body.~~

**(42a) For class III devices a manufacturer may consult voluntarily an expert panel on its clinical development strategy and on proposals for clinical investigations.**

(43) It is necessary, in particular for the purpose of the conformity assessment procedures, to maintain the division of medical devices into four product classes in line with international practice. The classification rules, which are based on the vulnerability of the human body taking into account the potential risks associated with the technical design and manufacture of the devices, need to be adapted to technical progress and experience gained from vigilance and market surveillance. To maintain the same level of safety as provided by Directive [90/385/EEC](#), active implantable medical devices and their accessories should be in the highest risk class.

- (43a) Rules applied to invasive devices did not sufficiently consider the level on invasiveness and potential toxicity of products which were introduced into the human body. In order to achieve a suitable risk based classification of substance-based medical devices, it is necessary to introduce specific classification rules for these types of devices. The classification criteria should take into account the place where the device performs its action in or on the human body or is introduced or applied and cases where a systemic absorption of the substance, or the product(s) of its metabolism, is present.***
- (44) The conformity assessment procedure for class I devices should be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products. For medical devices in classes IIa, IIb and III, an appropriate level of involvement of a notified body should be compulsory, ~~with medical devices in class III requiring explicit prior approval of their design and manufacture before they can be placed on the market.~~
- (45) The conformity assessment procedures should be simplified and streamlined whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.
- (45a) It is appropriate that certificates of free sale contain information that makes it possible to use the European databank on medical devices (Eudamed) in order to obtain information on the device and in particular whether it is on the market, withdrawn from the market or recalled and on any certificate on its conformity.***
- (46) To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements should be based on clinical data that, for class III medical devices and implantable medical devices should, as a general rule, be sourced from clinical investigations to be carried out under the responsibility of a sponsor who can be the manufacturer or another legal or natural person taking responsibility for the clinical investigation.

- (47) The rules on clinical investigations should be in line with major international guidance in this field, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects *to facilitate that the results of clinical investigations conducted in the Union ~~to~~ could be accepted as documentation outside the Union and to facilitate that results of clinical investigations conducted outside the Union in accordance with international guidelines can be accepted within the Union.* ~~and In addition the rules should be in line with~~ the most recent (2008) version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects ~~to ensure that clinical investigations conducted in the Union are accepted elsewhere and that clinical investigations conducted outside the Union in accordance with international guidelines can be accepted under this Regulation.~~
- (48) An electronic system should be set up at Union level to ensure that every clinical investigation is *recorded and reported* in a publicly accessible database. To protect the right to the protection of personal data, recognised by Article 8 of the Charter of Fundamental Rights of the European Union, no personal data of subjects participating in a clinical investigation should be recorded in the electronic system. To ensure synergies with the area of clinical trials on medicinal products, the electronic system on clinical investigations on medical devices should be interoperable with the EU database to be set up for clinical trials on medicinal products for human use.

- (49) ~~Where a Sponsors of clinical investigations is~~ to be conducted in more than one Member State, **Member States** should be given **have** the possibility **to allow the sponsor** to submit a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety related aspects of the investigational device and of the scientific design of the clinical investigation to be conducted in several Member States, such single application should facilitate the **voluntary** coordination between the Member States under the direction of a coordinating Member State. The coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a clinical investigation, including informed consent. ~~Each Member State should retain the ultimate responsibility for deciding whether the clinical investigation may be conducted on its territory.~~ **The Commission, collecting experiences of this voluntary coordination between Member states, should draw up a report and propose a review of the relevant provisions on a coordinated assessment procedure.**
- (50) Sponsors should report certain adverse events **and device deficiencies** occurring during clinical investigations to the Member States concerned, ~~which~~ **Member States** should have the possibility to terminate or suspend the investigations if considered necessary to ensure a high level of protection of the subjects enrolled in a clinical investigation. Such information should be communicated to the other Member States.
- (51) This Regulation should ~~only~~ cover clinical investigations **intended to gather clinical evidence and** which pursue regulatory purposes laid down in this Regulation **as well as setting out basic requirements regarding ethical and scientific assessments for other types of clinical investigations of medical devices.**

- (51a) Manufacturers should play an active role during the post-market phase by systematically and actively gathering information from post-market experience with their devices in order to update their technical documentation and cooperate with the national competent authorities in charge of vigilance and market surveillance activities. To this end manufacturers should establish a comprehensive post-market surveillance (PMS) system, set up under the quality management system and based on a PMS plan. Relevant data and information gathered ~~for~~ within the PMS, as well as lessons learned from any implemented preventive and/or corrective actions, should be used to update any relevant part of technical documentations, such as risk assessment, clinical evaluation and should serve the purpose of transparency.***
- (52) In order to better protect health and safety regarding devices on the market, the vigilance system for medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.
- (53) Healthcare professionals and patients should be empowered to report suspected serious incidents at national level using harmonised formats. The national competent authorities should inform manufacturers and share the information with their peers when they confirm that a serious incident has occurred in order to minimise recurrence of those incidents.
- (54) The assessment of reported serious incidents and field safety corrective actions should be conducted at national level but coordination should be ensured where similar incidents have occurred or field safety corrective actions have to be carried out in more than one Member State with the objective of sharing resources and ensuring consistency regarding the corrective action.
- (55) The reporting of serious adverse events during clinical investigations and the reporting of serious incidents occurring after a medical device has been placed on the market should be clearly distinguished to avoid double reporting.

- (56) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.
- (56a) *Any statistically significant increase in the number or severity of incidents or expected side effects that could have a significant impact on the risk-benefit determination and which may lead to unacceptable risks should be reported to the competent authorities in order to permit their assessment and the adoption of appropriate measures.*
- ~~(57) The Member States shall levy fees for the designation and monitoring of notified bodies to ensure sustainability of the monitoring of those bodies by Member States and to establish a level playing field for notified bodies.~~
- (58) Whilst this Regulation should not affect the right of Member States to levy fees for activities at national level, Member States should inform the Commission and the other Member States before they adopt the level and structure of the fees to ensure transparency.
- (59) An expert committee, the Medical Device Coordination Group (MDCG), composed of persons designated by the Member States based on their role and expertise in the field of medical devices and *in vitro* diagnostic medical devices should be established to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [.../...] on *in vitro* diagnostic medical devices<sup>32</sup>, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. ***The MDCG should be able to establish subgroups in order to provide necessary in-depth technical expertise in the field of medical devices and in vitro diagnostic medical devices.***

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<sup>32</sup> OJ L [...], [...], p. [...].



- (59a) *Experts panels and expert laboratories should be appointed by the Commission on the basis of up-to-date clinical, scientific or technical expertise, with the aim to provide scientific, technical and clinical assistance to the Commission, MDCG, manufacturers and notified bodies in relation to the implementation of this regulation. Moreover, experts panels should fulfil the tasks of providing an opinion to the clinical evaluation in the case of high risk implantable devices.*
- (60) Closer coordination between national competent authorities through information exchange and coordinated assessments under the direction of a coordinating authority is fundamental for ensuring a consistently high level of health and safety within the internal market, in particular in the areas of clinical investigations and vigilance. *The principle of coordinated exchange and assessment should also apply across other authority activities described in this Regulation, such as notified body designation and should be encouraged in the area of market surveillance of medical devices. This Joint working, coordination and communication of activities* should also lead to more efficient use of ~~searc~~ resources *and expertise* at national level.
- (61) The Commission should provide scientific, technical and corresponding logistic support to the coordinating national authority and ensure that the regulatory system for medical devices is effectively implemented at Union level based on sound scientific evidence.
- (62) The Union *and, where appropriate, the Member States* should actively participate in international regulatory cooperation in the field of medical devices to facilitate the exchange of safety-related information regarding medical devices and to foster the further development of international regulatory guidelines promoting the adoption of regulations in other jurisdictions with a level of health and safety protection equivalent to that set by this Regulation.

- (63) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles.
- (64) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the products subject to this Regulation that are similar to medical devices but do not necessarily have a medical purpose; adaptation of the definition of nanomaterial to technical progress and to developments at Union and international level; adaptation to technical progress ~~of the general safety and performance requirements~~, of the elements to be addressed in the technical documentation, of the minimum content of the EU declaration of conformity and of the certificates issued by notified bodies, ~~of the minimum requirements to be met by notified bodies, of the classification rules~~, **as well as** of the conformity assessment procedures, ~~and of the documentation to be submitted for the approval of clinical investigations~~; **certain aspects related to** the establishment of the UDI system; the information to be submitted for the registration of medical devices and certain economic operators; **the tasks of expert panels and expert laboratories** ~~the level and structure of fees for the designation and monitoring of notified bodies~~; the publicly available information in respect of clinical investigations; the adoption of preventive health protection measures at EU level; ~~and the tasks of and criteria for European Union reference laboratories and the level and structure of fees for scientific opinions delivered by them.~~

It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

- (65) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be *exercised* in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers<sup>33</sup>.
- (66) The advisory procedure should be used for the adoption of the form and presentation of the data elements of the manufacturers' summary of safety and clinical performance; ~~of the codes defining the notified bodies' scopes of designation~~; and of the model for certificates of free sale, given that those acts have a procedural character and do not directly *have an impact on* the health and safety at Union level.
- ~~(67) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the extension to the territory of the Union of a national derogation from the applicable conformity assessment procedures in exceptional cases; relating to the Commission's position whether a provisional national measure against a medical device presenting a risk or a provisional national preventive health protection measure is justified or not; and relating to the adoption of a Union measure against a medical device presenting a risk, imperative grounds of urgency so require.~~
- (68) To allow economic operators, notified bodies, Member States and the Commission to adapt to the changes introduced by this Regulation, it is appropriate to provide for a sufficient transitional period for that adaptation and for the organisational arrangements to be taken for its proper application. It is particularly important that by the date of application, a sufficient number of notified bodies are designated in accordance with the new requirements to avoid any shortage of medical devices on the market.

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<sup>33</sup> OJ L 55, 28.2.2011, p. 13.

(69) In order to ensure a smooth transition to the registration of medical devices, of relevant economic operators and of certificates, the obligation to submit the relevant information to the electronic systems put in place by this Regulation at Union level should, ***in case the corresponding IT systems are developed according to plan***, become fully effective only 18 months after the date of application of this Regulation. During this transitional period, ~~Article 10a and point (a) of Article 10b(1)~~ ***certain provisions*** of Directives 90/385/EEC and ~~Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive~~ 93/42/EEC should remain in force. However, economic operators and notified bodies who register in the relevant electronic systems provided for at Union level should be considered ***to be*** in compliance with the registration requirements adopted by the Member States pursuant to those provisions of the Directives to avoid multiple registrations. ***This transitional period should be prolonged in case the development of the IT systems is delayed.***

***(69b) In order to provide for a smooth introduction of the UDI system, the effective obligation to place the UDI carrier on the label of the device should moreover vary from one year to five years after the date of application of this Regulation depending upon the class of the medical device concerned.***

(70) Directives 90/385/EEC and 93/42/EEC should be repealed to ensure that only one set of rules applies to the placing of medical devices on the market and the related aspects covered by this Regulation.

***(70a) The European Data Protection Supervisor has given an opinion<sup>34</sup> pursuant to Article 28(2) of Regulation (EC) No 45/2001.***

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<sup>34</sup> OJ L XX, X.Y.20ZZ, p.X.

(71) Since the objective of this Regulation, namely to ensure high standards of quality and safety for medical devices, thus ensuring a high level of protection of health and safety of patients, users and other persons, cannot sufficiently be achieved by the Member States and can, by reason of the scale of the measure, 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 that objective.

HAVE ADOPTED THIS REGULATION:

## **Chapter I**

### **Scope and definitions**

#### *Article 1*

##### *Scope*

1. This Regulation ~~establishes~~ ***lays down*** rules ~~to be complied with by medical devices and accessories to medical devices that are placed~~ ***concerning the placing on the market, making available*** on the market or ~~putting~~ ***putting*** into service ~~of medical devices and accessories to medical devices for human use in the Union for human use.~~ ***This regulation also applies to clinical investigations on medical devices conducted in the Union.***

*1a. This regulation shall also apply to the groups of products without an intended medical purpose that are listed in Annex XV as from the date of entry into force of common specifications or the date of application of this Regulation, whichever is the latest, adopted pursuant to Article 7, taking into account the state of the art, and in particular existing standards for analogous devices with a medical purpose, based on a similar technology. The common specifications for a group of products listed in that annex shall address, at least, application of risk management and of the general safety and performance requirements set out in Annex I and clinical evaluation.*

*The necessary common specifications shall be adopted as soon as possible following entry into force of this Regulation and at the latest so that they enter into force on the date of application of this Regulation.*

*1b. For the purposes of this Regulation, medical devices, ~~and~~ accessories to medical devices **and products listed in Annex XV to which this Regulation applies pursuant to paragraph 1a** shall hereinafter be referred to as ‘devices’.*

*1c. ~~The~~ **Where justified in view of the similarity between a device with a medical purpose placed on the market and a product without a medical purpose in respect of their characteristics and risks,** the Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the list in Annex XV referred to in **Article 1(1a)** ~~the last subparagraph of number (1) of paragraph 1,~~ **by adding new groups of products** in the light of technical progress, **in order to protect the health and safety of users or other persons or other aspects of public health** ~~and taking into account the similarity between a medical device and a product without a medical purpose in respect of their characteristics and risks.~~*

2. This Regulation shall not apply to:

- (a) *in vitro* diagnostic medical devices covered by Regulation (EU) [.../...];
- (b) medicinal products *as defined in* ~~covered by Directive 2001/83/EC and advanced therapy medicinal products covered by Regulation (EC) No 1394/2007~~. In deciding whether a product falls under Directive 2001/83/EC ~~or Regulation (EC) No 1394/2007~~ or under this Regulation, particular account shall be taken of the principal mode of action of the product.
- (ba) *advanced therapy medicinal products covered by Regulation (EC) No 1394/2007;***
- (c) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market *or put into service* ~~or used in accordance with the manufacturer's instructions~~, such blood products, plasma or cells, except for devices referred to in paragraph 4;
- (d) cosmetic products covered by Regulation (EC) No 1223/2009;
- (e) transplants, tissues or cells of ~~human or~~ animal origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising tissues or cells of ~~human or~~ animal origin, or their derivatives, which are non-viable or are rendered non-viable.  
However, ~~human tissues and cells that are non-viable or are rendered non-viable and that have undergone only non-substantial manipulation, in particular those listed in Annex I of Regulation (EC) No 1394/2007, and products derived from such tissues and cells, shall not be considered devices manufactured utilising tissues or cells of human origin or their derivatives;~~
- (ea) *transplants, tissues or cells of human origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable;***
- (f) products, *other than those referred to in points (c), (e) and (ea)*, that contain or consist of *viable* biological substances or organisms, ~~other than those referred to in points (e) and (e), that are viable~~, including living micro-organisms, bacteria, fungi or virus *in order to achieve or support the intended purpose of the product;*
- (g) food covered by Regulation (EC) No 178/2002.

3. Any device which, when placed on the market or **put into service** ~~used in accordance with the manufacturer's instructions~~, incorporates as an integral part an *in vitro* diagnostic medical device as defined in Article 2 of Regulation (EU) [...] [on *in vitro* diagnostic medical devices] shall be governed by this Regulation, ~~unless it is covered by Article 1(3) of that Regulation~~. The relevant general safety and performance requirements set out in Annex I of that Regulation shall apply as far as the safety and performance of **to** the *in vitro* diagnostic medical device part ~~are concerned~~.

4. Where a device, when placed on the market or **put into service** ~~used in accordance with the manufacturer's instructions~~, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in Article 1(10) of that Directive, with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation.

However, if the action of the medicinal substance is **principal**, not ancillary to that of the device, the product shall be governed by Directive 2001/83/EC **or Regulation (EC) No 726/2004, as applicable**. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.

5. Where a device is intended to administer a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, that device shall be governed by this Regulation, without prejudice to the provisions of Directive 2001/83/EC **and Regulation (EC) No 726/2004** with regard to the medicinal product.

However, if the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, the product shall be governed by Directive 2001/83/EC **or Regulation (EC) No 726/2004, as applicable**. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.



5a. *Where a device, when placed on the market or put into service, incorporates, as an integral part, tissues or cells of human origin or their derivatives covered by Directive 2004/23/EC with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation. In this case the provisions for donation, procurement and testing laid down in Directive 2004/23/EC shall apply.*

*However, if the action of the tissues or cells or their derivatives is principal, not ancillary to that of the device and the product is not governed by Regulation (EC) No 1394/2007, the product shall be governed by Directive 2004/23/EC. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.*

6. This Regulation is a specific Union legislation within the meaning of Article 1(4) of Directive 2004/108/EC and within the meaning of Article 3 of Directive 2006/42/EC.

7. This Regulation shall not affect the application of Council Directive 96/29/Euratom nor of Council Directive 97/43/2013/59/Euratom.

8. This Regulation shall not affect national laws which require *concerning the organisation, delivery or financing of health services and medical care, such as, the requirement that certain medical devices may only be supplied on a medical prescription, the requirement that only certain health professionals or health care institutions may dispense or apply certain medical devices or that their application must be accompanied by specific professional counselling.*

8a. *This Regulation shall be without prejudice to national law regarding public access to official documents and regarding freedom of the press and freedom of expression in other media.*

9. ~~References to a Member State in this Regulation shall be understood as including any other country with which the Union has concluded an agreement which confers on that country the same status as a Member State for the purpose of application of this Regulation.~~

## Article 2

### Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

Definitions related to devices:

- (1) ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
  - investigation, replacement or modification of the anatomy or of a physiological *or pathological* process or state,
  - ~~control or support of conception,~~
  - ~~disinfection or sterilisation of any of the above mentioned products,~~
  - *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*
- and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

***Products specifically intended for the cleaning, disinfection or sterilisation of medical devices and devices for the purpose of control or support of conception shall be considered medical devices.***

~~The implantable or other invasive products, intended to be used for human beings, which are listed in Annex XV shall be considered medical devices, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.~~

- (2) ‘accessory to a medical device’ means an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable ~~or assist~~ the device(s) to be used in accordance with its/their intended purpose(s) **or to specifically and directly assist the medical functionality of the medical device(s) in view of its/their intended purpose(s);**
- (3) ‘custom-made device’ means any device specifically made in accordance with a written prescription of ~~a doctor of medicine, of a dental practitioner or of any other~~ person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient.

However, mass-produced devices which need to be adapted to meet the specific requirements of ~~a doctor of medicine, a dental practitioner or any other~~ professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of ~~doctors of medicine, dental practitioners or any other~~ authorised person shall not be considered to be custom-made devices;

- (4) ‘active device’ means any device, the operation of which depends on ~~a source of~~ electrical energy ~~or any a~~ source of **energy** other than that ~~directly~~ generated **by the human body for that purpose or** by gravity and which acts by changing the density of or converting this energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be considered to be active devices.

~~Stand alone software shall be considered an active device;~~

- (5) ‘implantable device’ means any device, including those that are partially or wholly absorbed, which is intended
- to be totally introduced into the human body or
  - to replace an epithelial surface or the surface of the eye,
- by clinical intervention and which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be considered an implantable device;
- (6) ‘invasive device’ means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body;
- (7) ‘generic device group’ means a set of devices having the same or similar intended purposes or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;
- (8) ‘single-use device’ means a device that is intended to be used on an individual patient during a single procedure.  
~~The single procedure may involve several uses or prolonged use on the same patient;~~
- (8a) ***‘falsified medical device’ means any device with a false presentation of its identity, and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights.***
- (9) ~~‘single-use device for critical use’ means a single-use device intended to be used for surgically invasive medical procedures;~~

- (9a) *‘procedure pack’ means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose ~~within a unique procedure~~;*
- (9b) *‘system’ means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose;*
- (10) ‘intended purpose’ means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements;
- (11) ‘label’ means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;
- (12) ‘instructions for use’ means the information provided by the manufacturer to inform the user of the device’s intended purpose and proper use and of any precautions to be taken;
- (13) ‘Unique Device Identification’ (‘UDI’) means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;
- (14) ‘non-viable’ means having no potential for metabolism or multiplication;
- (14a) *‘derivative’ means a “non-cellular substance” extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case shall not contain any cells or tissues;*

(15) ‘nanomaterial’ means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm;

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials;

(15aa) *‘particle’*, for the purposes of the definition of nanomaterial *in paragraph 1(15)*, ~~‘particle’, ‘agglomerate’ and ‘aggregate’ are defined as follows:~~ ‘particle’ means a minute piece of matter with defined physical boundaries;

(15ab)– ‘agglomerate’, *for the purposes of the definition of nanomaterial in paragraph 1(15)*, means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;

(15ac)– ‘aggregate’, *for the purposes of the definition of nanomaterial in paragraph 1(15)*, means a particle comprising of strongly bound or fused particles;

(15a) *‘performance’ means the ability of a device to achieve its intended purpose as claimed by the manufacturer;*

(15b) *‘safety’ means the absence of unacceptable risks, when using the device according to the ~~manufacturer’s instructions for use~~ intended purpose given by the manufacturer;*

(15d) *‘risk’ means the combination of the probability of occurrence of harm and the severity of that harm;*

*(15e) ‘benefit-risk determination’ means the integration of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the ~~instructions of use~~ intended purpose given by the manufacturer;*

*(15f) ‘compatibility’ is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to:*

- perform without losing or compromising the ability to perform as intended, and/or*
- integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or*
- be used together without conflict/interference or adverse reaction.*

*(15g) ‘interoperability’ is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to*

- exchange information and use the information that has been exchanged for correct execution of specified function without changing the content of the data, and/or*
- communicate with each other, and/or*
- work together as intended.*

Definitions related to the making available of devices:

*(16) ‘making available on the market’ means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;*

- (17) ‘placing on the market’ means the first making available of a device, other than an investigational device, on the Union market;
- (18) ‘putting into service’ means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

Definitions related to economic operators, users and specific processes:

- (19) ‘manufacturer’ means the natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under his name or trademark.

**(19a) ‘fully refurbishing’**, for the purposes of the definition of manufacturer, ~~fully refurbishing is defined as~~ **means** the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;

- (20) ‘authorised representative’ means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, **located outside the European Union**, to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

- (21) ‘importer’ means any natural or legal person established within the Union who places a device from a third country on the Union market;

- (22) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market;



- (23) ‘economic operators’ means the manufacturer, the authorised representative, the importer, ~~and~~ the distributor *and the person referred to in Article 20 (1) and 20 (3)*;
- (24) ‘health institution’ means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health;
- (25) ‘user’ means any healthcare professional or lay person who uses a device;
- (26) ‘lay person’ means an individual who does not have formal education in a relevant field of healthcare or medical discipline;
- (27) ‘reprocessing’ means the process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the used device;

Definitions related to conformity assessment:

- (28) ‘conformity assessment’ means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;
- (29) ‘conformity assessment body’ means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;
- (30) ‘notified body’ means a conformity assessment body designated in accordance with this Regulation;
- (31) ‘CE marking of conformity’ or ‘CE marking’ means a marking by which the manufacturer indicates that the device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;

Definitions related to clinical evaluation and clinical investigations:

- (32) ‘clinical evaluation’ means ~~the assessment and analysis of~~ ***a systematic and planned process to continuously generate, collect, analyse and assess the*** clinical data pertaining to a device in order to verify the safety and performance of the device when used as intended by the manufacturer;
- (33) ‘clinical investigation’ means any systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a device;
- (34) ‘investigational device’ means any device being assessed for safety and/or performance in a clinical investigation;
- (35) ‘clinical investigation plan’ means ~~the~~ ***a document(s) that describes*** ~~setting out the~~ rationale, objectives, design, ***methodology, monitoring, statistical considerations*** and ***organisation*** ~~proposed analysis, methodology, monitoring, conduct and record keeping of a~~ the clinical investigation;
- (36) ‘clinical data’ means the information concerning the safety or performance that is generated from the use of a device and that are sourced from the following:
- clinical investigation(s) of the device concerned,
  - clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated,
  - ~~published and/or unpublished~~ reports ***published in peer reviewed scientific literature*** on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated,
  - ~~the manufacturer’s post-market clinical follow-up (‘PMCF’);~~
  - ***other clinical data coming from the post-market surveillance system, including in particular the post-market clinical follow-up;***
- (37) ‘sponsor’ means an individual, company, institution or organisation which takes responsibility for the initiation, ~~for the~~ ***and management and for setting up the financing*** of a ***the*** clinical investigation;

- (37a) 'subject' means an individual who participates in a clinical investigation;*
- (37b) 'clinical evidence' means the clinical data pertaining to a device of sufficient amount and quality to allow a qualified assessment of whether the device achieves the intended clinical benefit(s) and safety, when used as intended by the manufacturer;*
- (37c) 'clinical performance' means the ability of a device to achieve its intended purpose as claimed by the manufacturer, including any direct or indirect medical effects on humans as well as the clinical benefit on patients resulting from the technical or functional, including diagnostic characteristics of a device, when used as intended by the manufacturer;*
- (37d) 'clinical benefit' means the positive impact of a device on the health of an individual, to be specified as meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis or a positive impact on patient management or public health;*
- (37h) 'investigator' means an individual responsible for the conduct of a clinical investigation at a clinical investigation site;*
- (37k) 'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation;*
- (37l) 'ethics committee' means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations;*

- (38) ‘adverse event’ means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device;
- (39) ‘serious adverse event’ means any adverse event that led to any of the following:
- death,
  - serious deterioration in the health of the subject, that resulted in any of the following:
    - (i) life-threatening illness or injury,
    - (ii) permanent impairment of a body structure or a body function,
    - (iii) hospitalisation or extending the duration of hospitalisation,
    - (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
    - (v) *chronic disease*,
  - foetal distress, foetal death or a congenital abnormality or birth defect;
- (40) ‘device deficiency’ means any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in the information supplied by the manufacturer;

Definitions related to *post-market surveillance*, vigilance and market surveillance:

**(40a) ‘post market surveillance’ means all activities carried out by the manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from their devices placed on the market, made available or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.**

- (40b) *'market surveillance' means the activities carried out and measures taken by public authorities to check and ensure that ~~products~~ devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;*
- (41) 'recall' means any measure aimed at achieving the return of a device that has already been made available to the end user;
- (42) 'withdrawal' means any measure aimed at preventing a device in the supply chain from further being made available on the market;
- (43) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market *including use-error due to ergonomic features*, any inadequacy in the information supplied by the manufacturer and any ~~unexpected~~ undesirable side-effect;
- (44) 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:
- death of a patient, user or other person,
  - temporary or permanent serious deterioration of the patient's, user's or other person's state of health,
  - serious public health threat;
- (44a) *'serious public health threat' means any event type, which could results in imminent risk of death, serious deterioration in state of health, or serious illness that may require prompt remedial action, and that may causes significant morbidity or mortality in humans or that is unusual or unexpected for the given place and time;*
- (45) 'corrective action' means action taken to eliminate the cause of a potential or real non-conformity or other undesirable situation;

(46) ‘field safety corrective action’ means corrective action taken by the manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;

(47) ‘field safety notice’ means the communication sent by the manufacturer to users or customers in relation to a field safety corrective action;

~~(48) ‘market surveillance’ means the activities carried out and measures taken by public authorities to **check and** ensure that products comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;~~

Definitions related to standards and other technical specifications:

(49) ‘harmonised standard’ means a European standard as defined in Article 2(1)(c) of Regulation (EU) No [Ref. of future Regulation on European standardisation];

(50) ‘common ~~technical~~ specifications’ (*CS*) means a document other than a standard that prescribes technical **and/or clinical** requirements that provide a means to comply with the legal obligations applicable to a device, process or system.

~~2. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the list in Annex XV referred to in the last subparagraph of number (1) of paragraph 1, in the light of technical progress and taking into account the similarity between a medical device and a product without a medical purpose in respect of their characteristics and risks.~~

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to adapt the definition of nanomaterial set out in number (15) of paragraph 1 in view of technical and scientific progress and taking into account definitions agreed at Union and international level.

### Article 3

#### Regulatory status of products

1. ~~The~~ **Without prejudice to Article 2(2) of Directive 2001/83, at a duly substantiated request of a Member State, the Commission may shall, at the request of a Member State or on its own initiative after consulting the MDCG,** by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory to a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).
  - 1a. **The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1.**
2. The Commission shall ensure the sharing of expertise between Member States, in the fields of medical devices, *in vitro* diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.

## Chapter II

### Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement

#### *Article 4*

##### *Placing on the market and putting into service*

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.
2. A device shall meet the general safety and performance requirements which apply to it, taking into account its intended purpose. General safety and performance requirements are set out in Annex I.
3. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 49.
4. Devices that are manufactured and used within a single health institutions shall be considered as being put into service. ~~The provisions regarding CE marking referred to in Article 18 and the obligations laid down in Articles 23 to 27 shall not apply to those devices, provided that manufacture and use of those devices occur under the health institution's single quality management system.~~



- 4a. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that the following conditions are met:**
- (aa) the device is not transferred to another legal entity,**
  - (a) manufacture and use of the devices occur under appropriate quality management systems,**
  - (b) the health institution establishes in its documentation that it has given due consideration as to whether the target patient group's specific needs cannot be met or cannot be met at the appropriate level of performance by an equivalent device available on the market,**
  - (c) the health institution provides information on an annual basis on the use of such devices to their competent authority, which shall include a justification of their manufacturing, modification and use,**
  - (d) the health institution draws up a declaration, that it shall make publicly available, including:**
    - the name and address of the manufacturing health institution;**
    - the details necessary to identify the devices;**
    - a declaration that the devices meet the general safety and performance requirements set out in Annex I of this Regulation and, where applicable, information on which requirements are not fully met with reasoned justification,**
  - (da) the health institution draws up documentation, allowing an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I of this Regulation are met;**
  - (e) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in the previous sub-paragraph, and**
  - (f) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.**

*Member States may require that the health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.*

*These provisions do not apply to devices which are manufactured on an industrial scale.*

5. The Commission *may adopt implementing acts to ensure the uniform application of Annex I. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).* ~~shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance requirements set out in Annex I, including the information supplied by the manufacturer.~~

#### *Article 5*

##### *Distance sales*

1. A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation ~~at the latest~~ when the device is placed on the market.
2. Without prejudice to national legislation regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, ***whether in return for payment or free of charge***, for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC or by other means of communication, ***directly or through intermediaries***, to a natural or legal person established in the Union shall comply with this Regulation.

3. *Upon request by a competent authority, the natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.*
4. *A Member State may, on grounds of protection of public health, require a provider of information society services as defined in Article 1(2) of Directive 98/34/EC to cease its activity.*

#### *Article 6*

##### *Harmonised standards*

1. Devices which are in conformity with the relevant harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

The first subparagraph shall also apply to system or process requirements to be fulfilled by economic operators or sponsors in accordance with this Regulation, including those related to the quality management system, risk management, the post-market surveillance ~~plan~~ **system**, clinical investigations, clinical evaluation or post-market clinical follow-up.

2. Reference to harmonised standards also includes the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, ***provided references to those monographs have been published in the Official Journal of the European Union.***

## Article 7

### *Common ~~technical~~ specifications*

1. ~~Where~~ ***Without prejudice to Article 1(1a) and 15 and the deadline laid down therein,*** ***where*** no harmonized standards exist or where relevant harmonised standards are not sufficient, the Commission, ***after having consulted the MDCG,*** ~~shall be empowered to~~ ***may*** adopt common ~~technical~~ specifications (ETS CS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II ~~or~~, the clinical evaluation and post-market clinical follow-up set out in Annex XIII ***or the requirements regarding clinical investigation set out in Annex XIV.*** The ETS CS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 88(3).
2. Devices which are in conformity with the ETS CS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those ETS CS or parts thereof.
3. Manufacturers shall comply with the ETS CS unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.
4. ***Notwithstanding paragraph 3, manufacturers of products listed in Annex XV shall comply with the relevant common specifications for those products.***

## Article 8

### *General obligations of the manufacturer*

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

- 1a. Manufacturers shall establish, execute, maintain and document a system for risk management as described in Section 1a in Annex I.**
- 1b. Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 49 and Annex XIII, including post-market clinical follow-up.**
2. Manufacturers, *of devices other than custom made devices* shall draw up **and keep up to date** the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II **and IIa**.

The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annexes II **and IIa**.

- 2a. Manufacturers of custom-made devices ~~devices~~ shall draw up, keep up to date and keep available to competent authorities documentation pursuant to Section 2 of Annex XI.**
3. Where compliance of a device with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than custom-made or investigational devices, shall draw up an EU declaration of conformity in accordance with Article 17, and affix the CE marking of conformity in accordance with Article 18.
- 3b. Manufacturers shall comply with the obligations related to the UDI system referred to in Articles 24 and with the registration obligations referred to in Article 24a, 24b and 25a.**

4. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any ~~supplement~~ **amendments and supplements**, issued in accordance with Article 45, available to the competent authorities for a period of at least five years after the last device covered by the declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.

~~Upon Where the technical documentation is voluminous or held in different locations, the manufacturer shall provide, upon request by a competent authority,~~ **the manufacturer shall provide the full technical documentation or** a summary technical documentation (STED) ~~and grant access to the full technical documentation upon~~ **as indicated in the** request.

**A manufacturer with registered place of business outside the Union shall, in order to allow the authorised representative to fulfil the tasks mentioned in Article 9, paragraph 3 ensure that the authorised representative has ~~to~~ the necessary documentation permanently available.**

5. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in product design or characteristics and changes in the harmonised standards or ~~ETS CS~~ CS by reference to which conformity of a product is declared shall be adequately taken into account *in a timely manner*. Proportionate to the risk class and the type of device, manufacturers of devices, other than ~~custom-made~~ or investigational devices, shall ~~institute~~ *establish, document, implement, maintain, and keep up to date and continually improve* a quality management system that shall *ensure compliance with this regulation in the most effective manner*.

*The quality management system consists of all parts and components of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It is managing the structure, responsibilities, procedures, processes and management resources to implement the needed principles and actions to achieve compliance with the provisions of this regulation.*

*The quality management system shall address at least the following aspects:*

- (aa) a strategy for regulatory compliance, including compliance with conformity assessment procedures and management of modifications to the devices covered by the system;*
- (ab) identification of applicable general safety and performance requirements and exploration of options to address these;*
  - (a) the responsibility of the management;
  - (b) resource management, including selection and control of suppliers and sub-contractors;
- (ba) risk management according to ~~section 1a~~ Chapter I of Annex I;*
- (bc) clinical evaluation, according to Article 49 and Annex XIII, including post-market clinical follow-up;*
- (c) product realisation, including planning, design, development, production and service provision;*
- (ca) control of the UDI-Code assignments to all relevant devices ensuring consistency of information provided according to Article 24a and 24b;*

- (cb) *setting-up, implementation and maintenance of a systematic post-market surveillance system according to Article 60a;*
- (cc) *handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;*
- (cd) *processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;*
- (ce) *management of corrective and preventive actions and verification of their effectiveness;*
- (d) processes for monitoring and measurement of output, data analysis and product improvement.

6. Proportionate to the risk class and the type of device, manufacturers of devices, ~~other than custom-made devices,~~ shall ~~institute~~ **implement** and keep up to date **the** systematic ~~procedure to collect and review experience gained from their devices placed on the market or put into service and to apply any necessary corrective action, hereinafter referred to as 'post-market surveillance plan'~~ **system referred to in Article 60a**. ~~The post-market surveillance plan shall set out the process for collecting, recording and investigating complaints and reports from healthcare professionals, patients or users on suspected incidents related to a device, keeping a register of non-conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices. Part of the post-market surveillance plan shall be a plan for post-market clinical follow-up in accordance with Part B of Annex XIII. Where post-market clinical follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan.~~

~~If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures.~~



7. Manufacturers shall ensure that the device is accompanied by the information to be supplied in accordance with Section 19 of Annex I in an official Union language(s) ~~which can be easily understood by the intended user or patient~~ *determined by*. ~~The language(s) of the information to be supplied by the manufacturer may be determined by the law of the~~ Member State where the device is made available to the user or patient. ***The particulars on the label shall be easily legible, clearly comprehensible and indelible.***
8. Manufacturers who consider or have reason to believe that a device which they have placed on the market ***or put into service*** is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the distributors and, where applicable, the authorised representative ***and the importers*** accordingly.

***Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 45, in particular, of the non-compliance and of any corrective action taken.***

- 8a. ***Manufacturers shall have a system for reporting of incidents and field safety corrective actions as described in Article 61.***

9. Manufacturers shall, ~~in response to a~~ **upon** reasoned request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language ~~which can be easily understood by that authority~~ **determined by the Member State concerned. The competent authority where the manufacturer has his registered place of business may require that the manufacturer provide samples of the device free of charge or, where impracticable, grant access to the device.** ~~They~~ **Manufacturers** shall cooperate with ~~that a~~ **competent** authority, at its request, on any corrective action taken to ~~mitigate or, where reasonably practicable~~ **eliminate or, if that is not possible, mitigate** the risks posed by devices which they have placed on the market or put into service.

*If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may take all appropriate measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it ~~withdraw the device until he cooperates or provides complete and correct information. it has been demonstrated that it is in conformity with the essential requirements.~~*

10. 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 25.
13. *Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.*

*To this end, manufacturers shall consider taking out appropriate insurance or arranging for an equivalent financial guarantee, to cover the costs associated with defective devices.*

## Article 9

### Authorised representative

1. ~~A~~ **Where the** manufacturer of a device **is not established in any Member State**, ~~that is the device may only be~~ placed on the Union market, ~~or bears the CE marking without being placed on the Union market, who does not have a registered place of business in a Member State or does not carry out relevant activities at a registered place of business in a Member State~~, **shall if the manufacturer** designates a single authorised representative.
2. The designation shall **constitute the authorised representative's mandate, it shall** be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.
3. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative. **The authorised representative shall provide a copy of the mandate to the competent authority, upon request.**

The mandate shall allow and require the authorised representative to perform at least the following tasks in relation to the devices that it covers:

- (aa) **verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;**
- (a) keep **a copy of** the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any **amendments and** supplements issued in accordance with Article 45 at the disposal of competent authorities for the period referred to in Article 8(4);
- (ab) **comply with the registration obligations laid down in Article 24a, 24b and 25a;**

- (b) in response to a ~~reasoned~~ request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device *in an official Union language determined by the Member State concerned*;
- (ba) *forward to the manufacturer any request by a competent authority where he has his registered place of business for samples, or access to a device and verify that the competent authority receives the samples or gets access to the device*;
- (c) cooperate with the competent authorities on any *preventive or* corrective action taken to ~~mitigate or, where reasonably practicable,~~ *eliminate or, if that is not possible, mitigate* the risks posed by devices;
- (d) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;
- (e) terminate the mandate if the manufacturer acts contrary to his obligations under this Regulation.

~~To allow the authorised representative to fulfil the tasks mentioned in this paragraph, the manufacturer shall at least ensure that the authorised representative has permanent immediate access to the necessary documentation in one of the official Union languages.~~

4. The mandate referred to in paragraph 3 shall not include the delegation of the manufacturer's obligations laid down in Article 8(1), *(1a)*, *(1b)*, (2), (3), *(3b)*, (5), (6), (7) and (8).

~~*4aa. Notwithstanding paragraph 4, the mandate referred to in paragraph 3 may include the delegation of the manufacturer's obligations laid down in points (cc), (cd) and (ce) of Article 8(5).*~~

*4a. Without prejudice to paragraph 4, where the manufacturer is not established in any Member State, and has not complied with the obligations laid down in Article 8, the authorised representative shall be legally liable for defective devices in accordance with Article 8(13).*

5. An authorised representative who terminates the mandate on the grounds referred to in point (e) of paragraph 3 shall immediately inform the competent authority of the Member State in which he is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.
6. Any reference in this Regulation to the competent authority of the Member State where the manufacturer has his registered place of business shall be understood as a reference to the competent authority of the Member State where the authorised representative, designated by a manufacturer referred to in paragraph 1, has his registered place of business.

### *Article 10*

#### *Change of authorised representative*

The modalities of a change of authorised representative shall be clearly defined in an agreement between the manufacturer, *where practicable* the outgoing authorised representative and the incoming authorised representative. This agreement shall address at least the following aspects:

- (a) the date of termination of the mandate with the outgoing authorised representative and date of beginning of the mandate with the incoming authorised representative;
- (b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;
- (c) the transfer of documents, including confidentiality aspects and property rights;
- (d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which he had been designated as authorised representative.

## Article 11

### General obligations of importers

1. Importers shall place on the Union market only devices that are in conformity with this Regulation.
2. ~~Before placing~~ ***In order to place*** a device on the market importers shall ~~ensure~~ ***verify*** the following:
  - (a) that the ***device has been CE marked and that the declaration of appropriate conformity of the device has been drawn up*** ~~assessment procedure has been carried out by the manufacturer;~~
  - (b) that an authorised representative in accordance with Article 9 has been designated by the manufacturer;
  - (c) ~~that the EU declaration of conformity and the technical documentation has been drawn up by the manufacturer;~~
  - (d) ~~that the device bears the required CE marking of conformity;~~
  - (e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use ~~and EU declaration of conformity;~~
  - (f) that, where applicable, a Unique Device Identification has been assigned by the manufacturer in accordance with Article 24.

Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not place the device on the market until it has been brought into conformity. ~~Where the device presents a risk, the importer~~ ***and*** shall inform the manufacturer and his authorised representative. ~~to that effect, as well as~~ ***Where the importer considers or has reason to believe that the device presents a serious risk or is falsified, he shall also inform*** the competent authority of the Member State in which he is established.

3. Importers shall indicate their name, registered trade name or registered trade mark and the address of their registered place of business at which they can be contacted and their location can be established on the device or on its packaging or in a document accompanying the device. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.
4. Importers shall ~~ensure~~ **verify** that the device is registered in the electronic system in accordance with Article 25(2) **24b and shall add their details to that registration. Importers shall also verify that the registration includes details on the authorised representative and, if appropriate, inform the authorised representative or the manufacturer.**
5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I **and shall comply with the conditions set by the manufacturer, where available.**
6. ~~When deemed appropriate with regard to the risks presented by a device, importers shall, in order to protect the health and safety of patients and users, carry out sample testing of marketed products, investigate complaints and~~ **Importers shall** keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and ~~shall keep~~ **provide** the manufacturer, authorised representative and distributors ~~informed of such monitoring~~ **with any information requested by them, in order to allow them to investigate complaints.**

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and his authorised representative. ~~and, if appropriate, take~~ ***Importers shall cooperate with the manufacturer, his authorised representative and the competent authorities to ensure that*** the necessary corrective action to bring that device into conformity, withdraw or recall it ***is taken***. Where the device presents a ***serious*** risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available ~~and, if applicable, the notified body that issued a certificate in accordance with Article 45 for the device in question~~, giving details, in particular, of the non-compliance and of any corrective action taken.
  
8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and his authorised representative.
  
9. Importers shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity ~~at the disposal of the market surveillance authorities and ensure that the technical documentation~~ and, if applicable, a copy of the relevant certificate including any ***amendments and*** supplements, issued in accordance with Article 45., ~~can be made available to those authorities, upon request. By written mandate, the importer and the authorised representative for the device in question may agree that this obligation is delegated to the authorised representative.~~



10. ~~Importers shall, in response to a request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product. This obligation shall be considered fulfilled when the authorised representative for the device in question provides the required information.~~ Importers shall cooperate with a competent ~~national authority~~ **authorities**, at **their** its request, on any action taken to ~~mitigate or, where reasonably practicable, eliminate~~ **or, if that is not possible, mitigate** the risks posed by devices which they have placed on the market. **Importers, upon request of a competent authority where the importer has his registered place of business, shall provide samples of the device free of charge or, where impracticable, grant access to the device.**

## Article 12

### *General obligations of distributors*

1. ~~When~~ **In the context of their activities, when** making a device available on the market, distributors shall act with due care in relation to the requirements applicable.

2. Before making a device available on the market distributors shall verify that the following requirements are met:
- (a) ~~the product~~ ***device*** ~~bears the required CE marking of conformity~~ ***has been CE marked and that the declaration of conformity of the device has been drawn up;***
  - (b) the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(7);
  - (c) ~~the manufacturer and, where applicable,~~ ***for imported devices***, the importer ~~have~~ ***has*** complied with the requirements set out in ~~Article 24 and Article 11(3) respectively;~~
  - (d) ***that, where applicable, a Unique Device Identification has been assigned by the manufacturer.***

***In order to meet the requirements referred to in subparagraphs (a) and (b) the distributor may apply a sampling method representative of products supplied by that distributor.***

Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not make the device available on the market until it has been brought into conformity ~~Where the device presents a risk, the distributor shall~~ ***and*** inform the manufacturer and, where applicable, his authorised representative, and the importer. ~~to that effect, as well as~~ ***Where the distributor considers or has reason to believe that the device presents a serious risk or is falsified, he shall also inform*** the competent authority of the Member State in which he is established.

3. Distributors shall ensure that, while ~~a~~ ***the*** device is under their responsibility, storage or transport conditions ~~do not jeopardise its compliance with the general safety and performance requirements set out in Annex I~~ ***comply with the conditions set by the manufacturer.***

4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer. ~~and make sure~~ *Distributors shall co-operate with the manufacturer and, where applicable his authorised representative and the importer, and with ~~any~~ competent authorities to ensure* that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where *the distributor considers or has reason to believe that* the device presents a *serious* risk, ~~they~~ *he* shall also immediately inform the competent authorities of the Member States in which ~~they~~ *he* made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.
5. Distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, his authorised representative *and the importer. They shall keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.*
6. Distributors shall, in response to a request from a competent authority, provide it with all the information and documentation *that is at its disposal and is* necessary to demonstrate the conformity of a device. This obligation shall be considered fulfilled when the authorised representative for the device in question, where applicable, provides the required information. Distributors shall cooperate with competent ~~national~~ authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. *Distributors, upon request of the competent authority where he has his registered place of business, shall provide free samples of the device or, where impracticable, grant access to the device.*

## Article 13

### *Person responsible for regulatory compliance*

1. Manufacturers shall have available within their organisation, at least one ~~qualified~~ person ***responsible for regulatory compliance*** who possesses expert knowledge in the field of medical devices. The expert knowledge shall be demonstrated by either of the following qualifications:
  - (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of ~~an~~ ***a course of study recognized as*** equivalent ~~course of study, in natural sciences,~~ ***by the Member State concerned, in*** medicine, pharmacy, engineering or another relevant ***scientific*** discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to ~~medical~~ devices;
  - (b) five years of professional experience in regulatory affairs ~~or~~ ***related to devices including experience*** in quality management systems ~~relating to medical devices~~.

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate their expert knowledge referred to in the first subparagraph by at least two years of professional experience within the relevant field of manufacture.

- 1a.* ~~This paragraph shall not apply to manufacturers of custom-made devices who are micro-enterprises as defined by~~ ***Micro and small enterprises within the meaning of*** Commission Recommendation 2003/361/EC ***are not required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.***

2. The ~~qualified~~ person ***responsible for regulatory compliance*** shall at least be responsible for ensuring the following matters:
  - (a) that the conformity of the devices is appropriately assessed ***checked in accordance with the quality management system under which these devices are manufactured*** before a ***product batch*** is released;
  - (b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;
  - (ba) ***that the post-market surveillance obligations in accordance with Article 8(6) are complied with;***
  - (c) that the reporting obligations in accordance with Articles 61 to 66 are fulfilled;
  - (d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued.
  
3. The ~~qualified~~ person ***responsible for regulatory compliance*** shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties, ***regardless of whether or not he is an employee of the organisation.***
  
4. Authorised representatives shall have ~~available within~~ ***permanently and continuously at their organisation disposal*** at least one ~~qualified~~ person ***responsible for regulatory compliance*** who possesses expert knowledge regarding the regulatory requirements for medical devices in the Union. The expert knowledge shall be demonstrated by either of the following qualifications:
  - (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of ~~an~~ ***a course of study recognised as equivalent by the Member State concerned, course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant scientific discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices;***
  - (b) five years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

## Article 14

### *Cases in which obligations of manufacturers apply to importers, distributors or other persons*

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if he does any of the following:
  - (a) makes available on the market a device under his name, registered trade name or registered trade mark, ***except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;***
  - (b) changes the intended purpose of a device already placed on the market or put into service;
  - (c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (19) of Article 2(1), assembles or adapts a device already on the market to its intended purpose for an individual patient.

2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:
  - (a) provision, including translation, of the information supplied by the manufacturer in accordance with Section 19 of Annex I relating to a device already placed on the market and of further information which is necessary in order to market the product in the relevant Member State;
  - (b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the product in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the package that shall ensure the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

3. A distributor or importer who carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate the activity carried out together with his name, registered trade name or registered trade mark and the address at which he can be contacted and his location can be established on the device or, where ~~that is not possible~~ *impracticable*, on its packaging or in a document accompanying the device.

He shall ensure that he has in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. Part of the quality management system shall be procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it in conformity with this Regulation.

4. Prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample or a mock-up of the relabelled or repackaged device, including any translated label and instructions for use. He shall submit to the competent authority a certificate, issued by a notified body referred to in Article 29, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.

## Article 15

### *Single-use devices and their reprocessing*

- 0. *Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this article.***
1. Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation.
- 1a. *By way of derogation from paragraph 1, as regards single-use devices that are reprocessed and used within a health institution, Member States may decide not to apply all ~~certain~~ rules relating to manufacturers' obligations laid down in this Regulation provided that they ensure that:***
- (a) *the safety and performance of the reprocessed device is equivalent to that of the original device and the requirements in points (aa), (a), (c), (d), (da), (e) and (f) of Article 4(4a) are complied with;***
  - (b) *the reprocessing is performed according to common specifications, detailing the requirements:***
    - *on risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original product as well as of its planned application after reprocessing,***
    - *on the validation of procedures for the entire process, including cleaning steps,***
    - *on the product release and performance testing, and***
    - *on the quality management system.***

***Member States shall notify the Commission and the other Member States of the national provisions, introduced pursuant to this paragraph and the grounds for introducing them. The Commission shall keep the information publicly available.***



- 1b. Member States may choose to apply provisions referred to in paragraph 1a also as regards single-use devices that are reprocessed by an external reprocessor at the request of a health institution provided that the reprocessed device in its entirety is returned to that health institution and the reprocessor complies with the requirements referred to in paragraph 1a (a) and (b).**
- 1bc. The Commission shall adopt the necessary common specifications referred to in paragraph 1a(b) by the date of application of this regulation. In case common specifications are not adopted by the date of application of this regulation, reprocessing shall be performed according to relevant harmonized standards and national provisions that ensure compliance with the requirements outlined in paragraph 1a(b). The compliance with the common specifications or, in the absence of common specifications, the relevant harmonized standards and the national provisions, shall be certified by a notified body.**
2. Only single-use devices that have been placed on the Union market in accordance with this Regulation, or prior to [date of application of this Regulation] in accordance with ~~Directive 90/385/EEC~~ or Directive 93/42/EEC may be reprocessed.
3. ~~In the case of reprocessing of single-use devices for critical use, only~~ **reprocessing of single-use devices** that is considered safe according to the latest scientific evidence may be carried out.
4. The Commission, by means of implementing acts, shall establish and regularly update a list of categories or groups of single-use devices ~~for critical use~~ which **cannot be reprocessed safely and therefore** may **under no circumstances** be reprocessed ~~in accordance with paragraph 3~~. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

5. The name and address of the legal or natural person referred to in paragraph 1 and the other relevant information in accordance with Section 19 of Annex I shall be indicated on the label and, where applicable, in the instructions for use of the reprocessed device. The name and address of the manufacturer of the original single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.
6. A Member State ***that permits reprocessing of single-use devices*** may maintain or introduce ***stricter*** national provisions ***restricting or*** prohibiting, within its territory, ~~on grounds of protection of public health specific to that Member State~~ the following:
  - (a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;
  - (b) the making available ***or further use*** of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of the national provisions ~~and the grounds for introducing them~~. The Commission shall keep the information publicly available.

#### Article 16

##### ~~Implant card~~ ***Information to be supplied to the patient with an implanted device***

1. The manufacturer of an implantable device shall provide together with the device ~~an implant card~~ ***the following***:
  - (a) ***information allowing the identification of the device, including the device name, serial number, batch code or lot number, the Unique Device Identification, the device model, reference or catalogue number, as well as the name, address and the URL of the website of the manufacturer;***
  - (c) ***any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;***
  - (d) ***any information about the expected lifetime of the device and any necessary follow-up;***
  - (e) ***any other information to assure a safe use of the device by the patient, including the information in Annex I, Section 19.3. Point (ob).***

**1a.** *The above mentioned information which shall be made available to for the particular patient who has been implanted with the device by any means that can allow a rapid access to the information and stated in the language(s) determined by the concerned Member State. The information shall be written in a way that is readily understood by a lay person. The information mentioned in this article shall be updated where appropriate and updates shall be available to the patient via the URL for the website mentioned in paragraph 1 point (a).*

**1aa.** *Member states shall require health institutions to make the information mentioned in this article available to patients who have been implanted.*

**1b.** *The Commission shall by means of implementing acts, establish a list of categories or groups of devices to which this Article shall not apply. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).*

**2.** ~~This card shall contain the following:~~

- ~~(a) the information allowing identification of the device, including the Unique Device Identification;~~
  - ~~(b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences or environmental conditions;~~
  - ~~(c) any information about the expected lifetime of the device and any necessary follow up.~~
- ~~The information shall be written in a way that is readily understood by a lay person.~~

## *Article 17*

### *EU declaration of conformity*

1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be translated into ~~the~~ **an** official Union language or languages required by the Member State(s) in which the device is made available.

2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires a declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device containing all information required for identification of the Union legislation to which the declaration relates.
3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress.

#### *Article 18*

##### *CE marking of conformity*

1. Devices, other than custom-made or investigational devices, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex IV.
2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile pack. Where that is not possible or not warranted on account of the nature of the device, it shall be affixed to the packaging. The CE marking shall also appear in the instructions for use and on the sales packaging where those are provided.
4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 42. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the legal requirements for CE marking.
6. Where devices are subject to other Union legislation concerning other aspects which also provide for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the provisions of the other legislation.

### *Article 19*

#### *Devices for special purposes*

1. Member States shall not create any obstacle to the following devices:
  - (a) investigational devices which are supplied to **an investigator** ~~doctor of medicine, a dental practitioner or another authorised person~~ for the purpose of clinical investigation if they meet the conditions laid down in Articles 50 to 60 and in Annex XIV;
  - (b) custom-made devices which are made available on the market if they comply with Article 42(7), **42(7a)** and Annex XI.

Those devices shall not bear the CE marking, with the exception of the devices referred to in Article 54.

2. Custom-made devices shall be accompanied by the statement referred to in **Section 1 of Annex XI** which shall be made available to the particular patient or user identified by name, an acronym or a numerical code.

Member States may require that the manufacturer of a custom-made device submit to the competent authority a list of such devices which have been made available in their territory.

3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create any obstacle to the showing of devices which do not comply with this Regulation, provided a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been made to comply with this Regulation.

## *Article 20*

### *Systems and procedure packs*

1. Any natural or legal person shall draw up a statement referred to in paragraph 2 if he puts devices bearing the CE marking together with the following other devices or products, in accordance with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack:
  - (a)- other devices bearing the CE marking;
  - (b)- *in vitro* diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) [.../...];
  - (c)- other products which are in conformity with the legislation applicable to those products ***only when they are used within the medical procedure or their presence in the system or procedure pack is justified.***
  
2. In the statement, the person referred to in paragraph 1 shall declare the following:
  - (a) that he verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and has carried out his operations in accordance with those instructions;
  - (b) that he 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;
  - (c) that the activity of putting devices and, if applicable, other products together as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market shall, at his choice, follow one of the procedures referred to in Annex VIII or in Part A of Annex X. The application of those Annexes and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile package is opened or damaged. The person shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions.
4. Where the system or procedure pack incorporate devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, *or where the sterilisation has not been carried out in accordance with the manufacturer's instructions* the system or procedure pack shall be treated as a device in its own right and shall be subjected to the relevant conformity assessment procedure pursuant to Article 42. *The natural or legal person shall assume the obligations incumbent on manufacturers.*
5. The systems or procedure packs referred to in paragraph 1 shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trade mark of the person referred to in paragraph 1 *and 3* as well as the address at which he can be contacted and his location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 19 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable to the devices put together in accordance with Article 8(4). Where these periods differ, the longest period shall apply.

## Article 21

### *Parts and components*

1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device ~~without significantly changing its performance or safety characteristics~~, shall ensure that the article does not adversely affect the safety and performance of the device. ~~Substantiating~~ **Supporting** evidence shall be kept available to the competent authorities of the Member States.
2. An article that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics of the device shall be considered a device.

## Article 22

### *Free movement*

***Except where otherwise provided in this regulation,*** Member States shall not refuse, prohibit or restrict the making available or putting into service within their territory of devices which comply with the requirements of this Regulation.



## Chapter III

### Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European databank on medical devices

#### Article 23

##### *Identification within the supply chain*

1. ***Distributors and importers shall co-operate with the manufacturer or authorized representative to achieve an appropriate level of traceability of devices.***
  
2. ***Economic*** ~~For devices, other than custom-made or investigational devices, economic operators shall be able to identify the following ***to the competent authority***, for the period referred to in Article 8(4):~~
  - (a) any economic operator to whom they have supplied a device;
  - (b) any economic operator who has supplied them with a device;
  - (c) any health institution ~~or healthcare professional~~ to whom they have supplied a device.~~Upon request, they shall inform the competent authorities thereof.~~

#### Article 23a

##### *Medical devices nomenclature*

***To facilitate the functioning of the European Databank on medical devices ('Eudamed') established pursuant to Article 27 the Commission shall ensure that a medical devices nomenclature shall be available free of charge to manufacturers and other natural or legal persons required to use nomenclature for the purpose of this regulation. The Commission shall also endeavour to ensure that that nomenclature is available to other stakeholders free of charge, where reasonably practicable.***

## Article 24

### Unique Device Identification system

1. ~~For devices, other than custom-made and investigational devices, a system for Unique Device Identification shall be put in place in the Union.~~ The **Unique Device Identification** ('UDI') system **described in Annex V Part C** shall allow the identification and **facilitate the** traceability of devices, **other than custom-made and investigational devices**, and shall consist of the following:
  - (a) production of a UDI that comprises the following:
    - (i) a device identifier ('**DI**') specific to a manufacturer and a device ~~model~~, providing access to the information laid down in Part B of Annex V;
    - (ii) a production identifier ('**PI**') that identifies **the produced device's unit and if applicable the packaged devices as specified in Annex V Part C** ~~data related to the unit of device production;~~
  - (b) ~~placement~~ **application** of the UDI on the label of the device **or on its package**;
  - (c) ~~storage of the UDI by the economic operators and the health institutions through electronic means;~~
  - (d) establishment of an electronic system on UDI ('**UDI database**') **according to Article 24a**.
  
2. The Commission shall designate one or several entities that operate a system for assignment of UDIs pursuant to this Regulation and that satisfy all of the following criteria:
  - (a) the entity is an organisation with legal personality;
  - (b) its system for the assignment of UDIs is adequate to identify a device through its distribution and use in accordance with the requirements of this Regulation;
  - (c) its system for the assignment of UDIs conforms to ~~the~~ **a** relevant international standards;
  - (d) the entity gives access to its system for the assignment of UDIs to all interested users according to a set of predetermined and transparent terms and conditions;

- (e) the entity undertakes the following:
- (i) to operate its system for the assignment of UDIs ~~for the period to be determined in the designation which shall at least be three~~ **ten** years after its designation;
  - (ii) to make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs ~~and concerning manufacturers that place an UDI on the label of their device in accordance with the entity's system;~~
  - (iii) to remain in compliance with the criteria for designation and the terms of designation ~~during the period for which it is designated.~~

*When designating entities, the Commission shall endeavour to ensure that UDI identifiers carriers are universally readable regardless of the system used by the assigning entity, with a view to minimising financial and administrative burdens for economic operators and health institutions.*

3. Before placing a device, ***other than a custom made device***, on the market, the manufacturer shall assign to the device ***and – if applicable – to all higher levels of packaging*** a UDI ***created in compliance with the rules of*** ~~provided by an entity designated by the Commission in accordance with paragraph 2, if that device belongs to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.~~
4. The UDI *carrier* shall be placed on the label of the device ***and on all higher levels of packaging. Higher levels of packaging do not include shipping containers.*** ~~in accordance with the conditions laid down by a measure referred to in point (c) of paragraph 7. It shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 61 and shall be included in the implant card referred to in Article 16. The device identifier shall appear on the EU declaration of conformity referred to in Article 17 and in the technical documentation referred to in Annex II.~~
- 4a. The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 61 and shall be included in the information to be provided to a patient implanted with a medical device referred to in Article 16.***

- 4b. The Basic UDI device identifier ('Basic UDI-DI' as defined in Annex V Part C) of the device shall appear on the EU declaration of conformity referred to in Article 17.**
- 4c. The manufacturer has to keep up-to-date a list of all applied UDI as part of the technical documentation referred to in Annex II.**
5. Economic operators and health institutions shall store and keep, **preferably** by electronic means, the ~~UDI device identifier and the production identifier~~ of the devices which they have supplied or they have been supplied with, if they belong to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.
- 5a. Member States shall encourage, and may require, health care professionals and health institutions to store and keep, preferably by electronic means, the UDI of the devices which they have been supplied with. With a view to ensuring a uniform approach to the manner in which the UDI of devices, categories or groups of devices which health institutions have been supplied with is to be stored, the Commission may adopt implementing acts pursuant to point (aa) of paragraph 7.**
- ~~6. The Commission, in cooperation with the Member States, shall set up and manage an electronic system on UDI to collate and process the information mentioned in Part B of Annex V. This information shall be accessible to the public.~~

7. The Commission shall be empowered to ~~may, by means of adopt delegated~~ **implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the Unique Device Identification System for any of the following aspects in accordance with Article 89:**

- (a) ~~determining~~ **the determination of** the devices, categories or groups of devices whose identification shall be based on the ~~to which the obligation laid down in paragraph 5 UDI shall apply~~ system as set out in paragraphs 1 to 6, and the timelines for implementing this. Following a risk-based approach, implementation of the UDI system shall be gradual, starting with devices falling in the highest risk class;
- (aa) **the determination of the devices, categories or groups of devices to which paragraph 5a shall apply;**
- (b) ~~specifying~~ **the specification of** the data to be included in the **UDI** production identifier (**'UDI-PI'**) ~~of specific devices or device groups which, following a risk-based approach, may vary depending on the risk class of the device;~~
- (c) ~~defining the obligations of economic operators, of health institutions and of professional users, in particular regarding allocation of the numeric or alphanumeric characters, placement of the UDI on the label, storage of information in the electronic system on UDI and use of the UDI in documentation and reporting related to the device provided for in this Regulation;~~

*Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).*

~~(d)~~7a. **The Commission shall be empowered to adopt delegated acts in accordance with Article 89:**

- (a) amending or supplementing the list of information set out in Part B of Annex V in the light of technical progress; **and**
- (b) **amending or supplementing Annex V in the light of international development in the field of unique device identification.**

8. When adopting the measures referred to in paragraph 7, the Commission shall take into account the following:
- (a) the protection of personal data;
  - (b) the legitimate interest in protecting commercially sensitive *confidential* information;
  - (c) the risk-based approach;
  - (d) the cost-effectiveness of the measures;
  - (e) the convergence of UDI systems developed at international level;
  - (f) *the need to avoid duplications in the UDI system;*
  - (g) *the needs of the health care systems of the Member States.*

#### *Article 24a*

##### *Electronic system on UDI*

- 1. The Commission, after consulting the MDCG shall set up and manage an electronic system on UDI ('UDI database') to validate, collate, process and make available to the public the information mentioned in Part B of Annex V.**
- 1a. When designing the UDI database the Commission shall consider the general principles on the UDI database as described in Annex V Part C section 5. The design shall, inter alia, be such that:**
- *no UDI production identifiers are included in the UDI database;*
  - *no commercially confidential product information shall be included in the UDI database.*
- 1b. The core data elements in the UDI database shall be accessible to the public free of charge.**
- 2. The technical design of the electronic system ~~must~~ shall ensure permanent accessibility on information stored in the UDI database and allow multi user access and automatic up and downloads of these information. The Commission shall provide for proper technical and administrative support to manufacturers and other users of the UDI database.**

3. *Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer or his authorised representative shall ensure that the information referred to in Part B of Annex V of the device in question are correctly submitted and transferred to the UDI database.*

#### **Article 24b**

##### **Process for registration of devices**

1. *Before placing a device, other than a custom made ~~or investigational~~ device, on the market, the manufacturer shall, in compliance with the rules of the designated issuing entities, assign a Basic UDI-DI as defined in Annex V Part C to the device.*
  - 1a. *Before placing on the market a system or procedure pack according to Article 20(1) and (3), that is not a custom made ~~or investigational~~ device, the responsible natural or legal person shall assign in compliance with the rules of the designated issuing entities to the system or procedure pack a Basic UDI-DI as detailed in Annex V Part C 6.3 and submit to the UDI database this Basic UDI-DI and the linked information referred to in Part B of Annex V.*
2. *Where a manufacturer of a device, other than custom made or investigational devices, applies a conformity assessment procedure according to Article 42 paragraph 3 first sentence, paragraph 4 or paragraph 5 the manufacturer shall submit to the UDI database the Basic UDI-DI and the linked information referred to in Part B of Annex V before placing the device on the market.*

3. *Where a manufacturer of devices, other than custom made or investigational devices, applies a conformity assessment procedure according to Article 42 paragraph 2 second sentence or paragraph 3 third sentence (EU technical documentation assessment and EU type-examination) the manufacturer shall assign the Basic UDI-DI (Annex V Part C) to the device before applying for a conformity assessment procedure by a notified body. The Notified Body shall reference the Basic UDI-DI on the certificate issued (Annex XII I 4.a)) and enter the information referred to in section 2.5 of Part A of Annex V. After the issuing of the relevant certificate and before placing the device on the market the manufacturer or his authorised representative shall submit to the UDI database the Basic UDI-DI and the linked information referred to in Part B of Annex V.*
- 3a *Before placing on the market a device, other than custom-made ~~or investigational~~ devices, the manufacturer shall submit to the Eudamed database the information referred to in section 2 of part A of annex V, with the exception of its section 2.5 and keep the information updated.*

#### *Article 25*

##### *Electronic system on registration of ~~devices and~~ economic operators*

1. The Commission, ~~in collaboration with the Member States~~ *after consulting the MDCG*, shall set up and manage an electronic system to *create the single registration number referred to in Article 25a and to* collate and process information that is necessary and proportionate to ~~describe and identify the device and to identify the manufacturer and, where applicable, the authorised representative and the importer.~~ The details regarding the information to be submitted by the economic operators are laid down in Part A of Annex V.
- 1b. *Member States may maintain or introduce national provisions on registration of distributors and importers of ~~a~~ devices which have been made available in their territory.*



2. ~~Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer or his authorised representative shall submit to the electronic system the information referred to in paragraph 1.~~
3. Within ~~one~~ **two** weeks after placing a device, other than a custom-made ~~or investigational~~ device, on the market, importers shall ~~submit to~~ **verify that the manufacturer or authorised representative has uploaded to** the electronic system the information referred to in paragraph 1 **and shall add their details to the relevant entry/entries.**

*Where applicable, importers shall also verify that the registration includes the details of the authorised representative and, if these details are not included, shall inform the relevant authorised representative.*

#### *Article 25a*

##### *Process for registration of manufacturers, ~~and~~ authorised representatives and importers, single registration number*

1. ~~The Manufacturers, or his authorised representatives and importers, who have~~ **not been registered before according to this article, shall submit to the electronic system the information referred to in Annex V Part A section 1 before placing a device, other than a custom-made ~~or investigational~~ device, on the market. In cases where the conformity assessment procedure requires the involvement of a notified body the information referred to in Annex V Part A shall be submitted to the electronic system before applying to a notified body.**
2. ~~After having verified the data entered pursuant to paragraph 1, by the manufacturer or his authorised representative the competent authority shall procure from the electronic system referred to in Article 25 a single registration number ('SRN') and issue it to the registrant manufacturer or his the authorised representative.~~

3. ***The manufacturer shall use the single registration number when applying to a notified body for certification according to Article 43 and for entering the electronic system on UDI (in order to fulfil their obligations according to Article 24a(3) and Article 24b(1a), (2), (3) and (3a)).***
4. Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.
5. Not later than ~~two~~ ***one*** years after submission of the information in accordance with paragraphs ~~2 and 3~~ ***1***, and then every second year ***thereafter***, the relevant economic operator shall confirm the accuracy of the data. ***Without prejudice to the economic operator's responsibility for the data, the competent authority shall verify the confirmed data referred to in Section 1 of Part A of Annex V.*** In the event of failure to confirm within six months of the due date, any Member State may take ***appropriate corrective*** measures ~~to suspend or otherwise restrict the making available of the device in question~~ within its territory until the obligation referred to in this paragraph is complied with.
6. The data contained in the electronic system shall be accessible to the public.
7. ~~The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending the list of information to be submitted as set out in Part A of Annex V in the light of technical progress.~~
- 7a. ***The competent authority may use the data to administer a fee to the manufacturer, or the authorised representative or the importer pursuant to Article 86.***

## Article 26

### *Summary of safety and clinical performance*

1. In the case of devices classified as class III and implantable devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance. It shall be written in a way that is clear to the intended user ***and, if relevant, to the patient and shall be made available to the public via Eudamed.*** The draft of this summary shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 42 and shall be validated by that body. ***After validation the notified body shall upload this summary report to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary report is available.***
  
- 1a. ***The summary of safety and clinical performance shall include at least the following aspects:***
  - (a) ***the identification of the device and the manufacturer, including the basic UDI-DI and the single registration number;***
  - (b) ***the intended purpose of the device, including indications, contra-indications and target populations;***
  - (c) ***a description of the device, including a reference to previous generation(s) or variants if such exist, and the description of the differences, as well as a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device;***
  - (d) ***possible diagnostic or therapeutic alternatives;***
  - (e) ***reference to harmonized standards and common specifications;***
  - (f) ***the summary of the clinical evaluation as referred to in annex XIII, and relevant information on the post-market clinical follow up;***
  - (g) ***suggested profile and training for users;***
  - (h) ***information on any residual risks and any undesirable effects, warnings and precautions.***

2. The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and clinical performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).

#### *Article 27*

##### *European databank on medical devices*

1. The Commission, **after consulting the MDCG**, shall develop and manage the European databank on medical devices (Eudamed) for the following purposes:
  - (a) to enable the public to be adequately informed about devices placed on the market, about the corresponding certificates issued by notified bodies and about the relevant economic operators;
  - (b) to enable **unique identification and to facilitate** traceability of devices within the internal market;
  - (c) to enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations ~~to be conducted in more than one Member State~~ to comply with ~~information~~ obligations under Articles 50 to 60;
  - (d) to enable manufacturers to comply with information obligations under Articles 61 to 66;
  - (e) to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well informed basis and to enhance the cooperation between them.

2. Eudamed shall include the following as ~~integral parts~~:
  - (aa) the electronic system on registration of devices referred to in Article 24b;**
    - (a) the electronic system on UDI referred to in Article 24a;
    - (b) the electronic system on registration of ~~devices and~~ economic operators referred to in Article 25;
  - (ba) the electronic system on notified bodies referred to in Article 33(9);**
  - (c) the electronic system on information **on applications for conformity assessment and** on certificates referred to in Article **43(1) and Article 45(4) and on summaries of safety and clinical performance referred to in Article 26;**
  - (d) the electronic system on clinical investigations referred to in Article 53,
  - (e) the electronic system on vigilance **and post-market surveillance** referred to in Article ~~62~~ **66a**;
  - (f) the electronic system on market surveillance referred to in Article ~~68~~ **75b**.
- 2a. When designing Eudamed the Commission shall give due consideration to the compatibility of national databases and national web-interfaces to allow for import and export of data.**
3. The data shall be entered into Eudamed by the Member States, notified bodies, economic operators and sponsors as specified in the provisions concerning the electronic systems referred to in paragraph 2. **The Commission shall provide for technical and administrative support to users of Eudamed.**
4. All the information collated and processed by 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 defined in the provisions referred to in paragraph 2.
5. Eudamed shall contain personal data only insofar as this is necessary for the electronic systems referred to in paragraph 2 to collate and process the information in accordance with this Regulation. Personal data shall be kept in a form which permits identification of the data subjects for no longer than the periods referred to in Article 8(4).

6. The Commission and the Member States shall ensure that the data subjects may effectively exercise their rights to information, to access, to rectify and to object in accordance with Regulation (EC) No 45/2001 and Directive 95/46/EC, respectively. They shall ensure that the data subjects may effectively exercise the right of access to data relating to them, and the right to have inaccurate or incomplete data corrected and erased. Within their respective responsibilities, the Commission and the Member States shall ensure that inaccurate and unlawfully processed data is deleted, in accordance with the applicable legislation. Corrections and deletions shall be carried out as soon as possible, but no later than within 60 days after a request is made by a data subject.
7. The Commission shall, by means of implementing acts, lay down the modalities necessary for the development and management of Eudamed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3). ***When adopting these implementing acts, the Commission shall ensure that, to the extent possible, the system develops so as to avoid any requirement of double entries of the same information within the same module or in different modules of the system.***
8. In relation to its responsibilities under this Article and the processing of personal data involved therein, the Commission shall be considered controller of Eudamed and its electronic systems.

#### *Article 27a*

##### *Functionality of the European database portal and the Electronic system on UDI*

1. ***The Commission shall, in collaboration with the MDCG, draw up the functional specifications for the European database referred to in article 27 and the Electronic system on UDI referred to in article 24a, together with the time frame for their implementation.***

2. *The Commission shall, on the basis of an independent audit report, inform the MDCG when it has verified that the European database and the Electronic system on UDI have achieved full functionality and the systems meet the functional specifications drawn up pursuant to paragraph 1.*
  
3. *The Commission shall, after consultation with the MDCG and when it is satisfied that the conditions referred to in paragraph 2 have been fulfilled, publish a notice to that effect in the Official Journal of the European Union.*

## Chapter IV

### Notified bodies

#### Article 28

##### *National authorities responsible for notified bodies for medical devices*

1. A Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out ~~third-party~~ conformity assessment ~~tasks~~ **activities** under this Regulation shall ***nominate*** ~~designate~~ an authority, ***which may consist of separate constituent entities under national law***, that shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors ~~or~~ ***and*** subsidiaries of those bodies, hereinafter referred to as the ‘national authority responsible for notified bodies’.
2. The national authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies.
3. ***The national authority responsible for notified bodies*** ~~It~~ shall be organised so that each decision relating to ***designation or*** notification ~~of a conformity assessment body~~ is taken by personnel different from those who carried out the assessment ~~of the conformity assessment body~~.
4. ***The national authority responsible for notified bodies*** ~~It~~ shall not perform any activities that ~~conformity assessment~~ ***notified*** bodies perform ~~nor provide consultancy services on a commercial or competitive basis~~.
5. The national authority responsible for notified bodies shall safeguard the confidentiality of the information it obtains. However, it shall exchange information on a notified body with other Member States, ~~and~~ the Commission ***and, when required, with other regulatory authorities***.



6. The national authority responsible for notified bodies shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

~~Where Without prejudice to Article 33(3), where a~~ **the** national authority is responsible for the designation of notified bodies in the field of products other than medical devices, **is a different authority than the national competent authority for medical devices, it shall ensure that the national competent authority responsible for medical devices is** shall be consulted on all **relevant** aspects specifically related to medical devices.

7. Member States shall **make publicly available general** ~~provide the Commission and the other Member States with~~ information on their procedures for **provisions on** the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and **on** ~~of any~~ changes **which have a significant impact on these tasks** thereto.

8. The national authority responsible for notified bodies shall ~~be peer reviewed every second year~~ **participate in the peer-review activities laid down in Article 38**. The peer review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. ~~In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer review.~~

~~The Member States shall draw up the annual plan for the peer review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission may participate in the review. The outcome of the peer review shall be communicated to all Member States and to the Commission and a summary of the outcome shall be made publicly available.~~

## Article 29

### *Requirements relating to notified bodies*

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary ***so they are qualified*** to fulfil their tasks for which they are designated in accordance with this Regulation. ~~Minimum~~ ***The*** requirements to be met by notified bodies are set out in Annex VI.
  - 1a. ***Notified bodies shall make available and submit upon request, all relevant documentation, including the manufacturer's documentation to the national authority responsible for notified bodies to allow it to conduct its assessment, designation, notification and monitoring and surveillance activities outlined within this Chapter.***
2. ~~The~~ ***In order to ensure the uniform application of the requirements set out in Annex VI, the*** Commission shall be empowered to ~~may~~ adopt delegated ***implementing*** acts in accordance with Article 889(3) ~~amending or supplementing the minimum requirements in Annex VI, in the light of technical progress and considering the minimum requirements needed for the assessment of specific devices, or categories or groups of devices.~~

## Article 30

### *Subsidiaries and subcontracting*

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the ~~relevant~~ ***applicable*** requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.
2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

3. Conformity assessment activities may be subcontracted or carried out by a subsidiary ~~only with the agreement of~~ ***provided that*** the legal or natural person that applied for conformity assessment ***has been informed of this***.
4. Notified bodies shall keep at the disposal of the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

#### *Article 31*

##### *Application by a conformity assessment body for ~~notification~~ designation*

1. A conformity assessment body shall submit an application for ~~notification~~ ***designation*** to the national authority responsible for notified bodies of the Member State in which it is established.
2. The application shall specify the conformity assessment activities ***as defined in this Regulation***, ~~the conformity assessment procedures~~ and the ***types of*** devices for which the body ***applies to be designated and for which involvement of a notified body is required*** ~~claims to be competent~~, supported by documentation proving compliance with all the requirements set out in Annex VI.

In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VI, ~~the relevant documentation may be submitted in form of~~ a valid certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008 ***may be submitted in support of these requirements and shall be taken into consideration during the assessment described in Article 32. However, the applicant shall make available the full documentation to demonstrate conformity with these requirements upon request.*** ~~The conformity assessment body shall be presumed to be in conformity with the requirements covered by the certificate delivered by such accreditation body.~~

3. After being designated, the notified body shall update the documentation referred to in paragraph 2 whenever relevant changes occur in order to enable the national authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VI.

### *Article 32*

#### *Assessment of the application*

1. The national authority responsible for notified bodies shall ***within 30 days*** check that the application referred to in Article 31 is complete and ***shall request the applicant to provide any missing information. Once the application is complete the national authority shall send it to the Commission along with a proposed timeframe for preliminary review and an indicative date for an on-site assessment.***

***The national authority shall review the application and supporting documentation in accordance with its own procedures and shall draw up a preliminary assessment report.***

2. ~~‡~~ ***The national authority responsible for notified bodies*** shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the Medical Device Coordination Group established by Article 78 ('MDCG'). ***The national authority responsible for notified bodies shall also indicate based on their assessment whether the on-site assessment date proposed in paragraph 1 remains valid.*** ~~Upon request by the Commission, the report shall be submitted by the authority in up to three official Union languages.~~

***Documents to support the application described in Article 31 shall be made available upon request.***

3. Within 14 days of the submission referred to in paragraph 2, the Commission, ***in conjunction with the MDCG***, shall ~~designate~~ ***assign*** a joint assessment team made up of ~~at least two~~ ***three*** experts, ***unless the specific circumstances require another number of experts***, chosen from ~~a~~ ***the*** list of experts who are qualified in the assessment of conformity assessment bodies ***referred to in Article 32a***. ~~The list shall be drawn up by the Commission in cooperation with the MDCG.~~ ***One*** ~~At least one~~ of these experts shall be a representative of the Commission who shall ~~lead~~ ***coordinate*** the ***activities of the*** joint assessment team.

***The joint assessment team shall be comprised of competent experts which reflect the conformity assessment activities and the types of devices which are subject to the application or, in particular when this procedure is initiated in accordance with Article 37 to ensure that the specific concern can be appropriately assessed.***

4. Within 90 days after ~~designation~~ ***assignment*** of the joint assessment team, ~~the national authority responsible for notified bodies and~~ the joint assessment team shall review the documentation submitted with the application in accordance with Article 31. ***The joint assessment team may provide feedback to or require clarification from the national authority responsible for notified bodies on the application and on the planned on-site assessment.***

***The national authority responsible for notified bodies together with 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 sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process. ~~Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 31(2), unless the Commission representative mentioned in Article 32(3) requests the on-site assessment.~~

***The on-site assessment of the applicant body shall be led by the national authority responsible for notified bodies.***

**4a.** Findings regarding non-compliance of a body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team with a view to finding common agreement **and resolution of any diverging opinions**, with respect to the assessment of the application. ~~Divergent opinions shall be identified in the assessment report of the national authority responsible.~~

*A list of non-compliances resulting from the assessment shall be presented by the national authority responsible for notified bodies to the applicant body at the end of the on-site assessment including a summary of the assessment delivered by the joint assessment team.*

*The national authority shall request a corrective and preventive action plan from the applicant body to be submitted within a specified timeframe to address the non-compliances.*

**4aa.** *The joint assessment team shall document any remaining diverging opinions within 30 days of completion of the on-site assessment with respect to the assessment and send these to the national authority responsible for notified bodies.*

- 4b. *The national authority responsible for notified bodies shall following receipt of a corrective and preventive action plan from the applicant body assess whether non-compliances identified during the assessment have been appropriately addressed. This plan shall include an indication of the root cause of the finding and a timeframe for implementation of the actions therein.*

*The national authority shall having confirmed the corrective and preventive action plan forward this plan and its opinion on this plan to the joint assessment team. The joint assessment team may request further clarification and modifications from the national authority responsible for notified bodies.*

*The national authority responsible for notified bodies shall draw up its final assessment report which shall include:*

- *the result of the assessment,*
- *confirmation that the corrective and preventive actions have been appropriately addressed and, where required, implemented,*
- *any remaining diverging opinion with the joint assessment team, and, where applicable,*
- *the recommended scope of designation.*

5. The national authority responsible for notified bodies shall submit its **final** assessment report and, **if applicable, the** ~~its draft notification~~ **designation** to the Commission, ~~which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages.~~

6. The joint assessment team shall provide its opinion *in a final report* regarding the assessment report *prepared by the national authority responsible for notified bodies* and, *if applicable*, the draft ~~notification~~ *designation* within 21 days of receipt of those documents ~~and to the~~ Commission, *which* shall immediately submit this opinion to the MDCG. Within ~~21~~ **42** days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft ~~notification~~ *designation* which the ~~relevant~~ national authority *responsible for notified bodies* shall duly take into consideration for its decision on the designation of the notified body.
7. The Commission may, by means of implementing acts, adopt measures setting out the modalities *specifying procedures and reports* for the application for ~~notification~~ *designation* referred to in Article 31 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

#### *Article 32a*

##### *Nomination of experts for joint assessment of applications for notification*

1. *The Member States and the Commission shall nominate experts qualified in the assessment of conformity assessment bodies in the field of medical devices to participate in the activities outlined in Article 32 and Article 38.*
2. *The Commission shall maintain a list of the experts nominated pursuant to paragraph 1, together with information on their specific competence and expertise. This list shall be made available to Member States competent authorities through the electronic system referred to in Article 27.*



## *Article 32b*

### *Language requirements*

*All documents required pursuant to Articles 31 and 32 shall be drawn up in a language or languages which shall be determined by the Member State concerned.*

*Member States, in applying the first sub-paragraph, shall consider accepting and using a commonly understood language in the medical field, for all or part of the documents concerned.*

*The Commission shall provide necessary translations of the documentation pursuant to Article 31 and 32, or parts thereof into an official Union language such that the documents can be readily understood by the joint assessment team designated in accordance with Article 32(3).*

## *Article 33*

### *~~Notification~~ Designation and notification procedure*

0. Member States may ~~notify~~ only **designate** conformity assessment bodies **for which the assessment pursuant to Article 32 was completed and** which satisfy the requirements set out in Annex VI.
1. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool developed and managed by the Commission.
2. ~~Member States may notify only conformity assessment bodies which satisfy the requirements set out in Annex VI.~~
3. ~~Where a national authority responsible for notified bodies is responsible for designation of notified bodies in the field of products other than medical devices, the competent authority for medical devices shall provide, prior to the notification, a positive opinion on the notification and its scope.~~

4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities *as defined in this Regulation*, ~~the conformity assessment procedures~~ and the type of devices which the notified body is authorised to assess *and, without prejudice to Article 35, any conditions associated with the designation.*
  
- 4a. The Commission *shall within six months of the entry into force of this Regulation* ~~may~~, by means of implementing acts, ~~set~~ *draw* up a list of codes and ~~the~~ corresponding types of devices to ~~define~~ *describe* the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the ~~advisory~~ *examination* procedure referred to in Article 88(2 3). *The Commission, after consulting the MDCG, may update this list inter alia based on information arising from the coordination activities described in Article 38.*
  
5. The notification shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the ~~opinion~~ *final report* of the joint assessment team and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.
  
6. The notifying Member State shall, *without prejudice to Article 35*, ~~provide~~ *inform* the Commission and the other Member States *of any conditions associated with the designation and with* ~~provide~~ documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VI. ~~It shall furthermore submit evidence of the availability of competent personnel for monitoring the notified body in accordance with Article 28(6).~~
  
7. Within 28 days of a notification, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the national authority responsible for notified bodies.

8. When a Member State or the Commission raises objections in accordance with paragraph 7, ~~the effect of the notification shall be suspended. In this case,~~ the Commission shall bring the matter before the MDCG within ~~15~~ **10** days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within ~~40~~ **28** days after the matter has been brought before it. ~~If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.~~

**8a. Where the MDCG, after having been consulted in accordance with paragraph 8, confirms the existing objection or raises another objection, the notifying Member State shall provide a written response to the MDCG opinion within 40 days of its receipt. The response shall address the objections raised in the opinion, and set out the reasons for the notifying Member State's decision to designate or not designate the conformity assessment body.**

9. Where no objection is raised in accordance with paragraph 7 or where the MDCG ~~or the Commission,~~ after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted ~~fully or partially,~~ **or where the notifying Member State having responded in accordance with paragraph 8a, decides to notify the designation of the conformity assessment body** the Commission shall publish the notification ~~accordingly~~ **within 14 days of receipt.**

**When publishing the notification in the database of notified bodies developed and managed by the Commission, the Commission shall also add the information relating to the notification of the notified body to the electronic system referred to in Article 27 along with the documents mentioned in paragraph 5 and the opinion and responses referred to in paragraphs 8 and 8a of this Article.**

10. The notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the notified body.

**11. The conformity assessment body concerned may perform the activities of a notified body only after the notification has become valid in accordance with paragraph 10.**

## Article 34

### *Identification number and list of notified bodies*

1. The Commission shall assign an identification number to each notified body for ~~which~~ the notification is accepted **as it becomes valid** in accordance with Article 33(10). It shall assign a single identification number even when the body is notified under several Union acts.
2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the **conformity assessment** activities **as defined in this Regulation and the types of devices** for which they have been notified, accessible to the public **in the database of notified bodies developed and managed by the Commission. It shall also make this list available on the electronic system referred to in Article 27.** The Commission shall ensure that the list is kept up to date.

## Article 35

### *Monitoring and assessment of notified bodies*

0. **Notified bodies shall, without delay, inform the national authority responsible for notified bodies of relevant changes which may affect their compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment activities relating to the devices for which they have been designated.**

1. The national authority responsible for notified bodies shall ~~continuously~~ **conduct** monitoring of the notified bodies **based on its territory and of their subsidiaries and subcontractors** to ensure ongoing compliance with the requirements **and the fulfilment of its obligations** set out in **this Regulation Annex VI**. The notified bodies shall, on request **from the national authority responsible for notified bodies**, supply all relevant information and documents, required to enable the authority, **the Commission and other Member States** to verify compliance with those criteria.

~~Notified bodies shall, without delay, inform the national authority responsible for notified bodies of any changes, in particular regarding their personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment procedures relating to the devices for which they have been designated.~~

2. **The national authority responsible for notified bodies shall receive a copy of all requests submitted by the Commission or by another Member State authority to notified bodies on its territory relating to conformity assessments such notified bodies have carried out.** Notified bodies shall respond without delay to **such** requests ~~relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission.~~ The national authority responsible for notified bodies of the Member State in which the body is established shall ~~enforce~~ **ensure that** requests submitted by authorities of any other Member State or by the Commission **are resolved** unless there is a legitimate reason for not doing so in which case both sides may consult the MDCG. ~~The notified body or their national authority responsible for notified bodies may request that any information transmitted to the authorities of another Member State or to the Commission shall be treated confidential.~~

3. At least once a year, the national authority responsible for notified bodies shall *re-assess* whether each notified body *and, when appropriate, the subsidiaries and subcontractors* under its responsibility still ~~satisfies~~ *satisfy* the requirements *and fulfil their obligations* set out in Annex VI. This ~~assessment~~ *review* shall include an on-site visit to each notified body *and, when necessary, to its subsidiaries and subcontractors*.

*The national authority responsible for notified bodies shall conduct its monitoring and assessment activities according to an annual assessment plan to ensure that it can effectively monitor the continued compliance of the notified body with the requirements of this Regulation. This plan shall provide a reasoned schedule for the frequency of assessment of the notified body and, in particular, associated subsidiaries and subcontractors. The authority shall submit its annual plan for monitoring or assessment for each notified body for which it is responsible to the MDCG and to the Commission.*

- 3a. *The monitoring of notified bodies by the national authority responsible for notified bodies shall include witnessed audits of the notified body personnel, including when necessary the personnel from subsidiaries and subcontractors, when conducting quality system assessments at a manufacturer's facility.*
- 3c. *The monitoring of notified bodies conducted by national authorities responsible for notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance systems to help guide its activities.*

*The national authority responsible for notified bodies shall provide for a systematic follow-up of complaints and other information, including from other Member States, which may indicate non-fulfilment of the obligations by a notified body or its deviation from common or best practice.*

- 3ca. *The national authority responsible for notified bodies may in addition to regular monitoring or on-site assessments conduct short-notice, unannounced or 'for-cause' reviews if needed to address a particular issue or to verify compliance.*

- 3cb. The national authority responsible for notified bodies shall assess the notified body assessments of manufacturers' technical and clinical documentation as further outlined in Article 35a.**
- 3d. The national authority responsible for notified bodies shall document and record any findings regarding non-compliance of the notified body with the requirements set out in Annex VI and shall monitor the timely implementation of corrective and preventive actions.**
4. Three years after notification of a notified body, and again every ~~third~~ **fourth** year thereafter, ~~the a complete re-~~assessment to determine whether the notified body still satisfies the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article **31 and 32(3) and (4)**. ~~At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body with the requirements set out in Annex VI.~~
- 4a. The Commission may, by means of implementing acts, modify the frequency of complete re-assessment referred to in the previous sub-paragraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).**
5. The Member States shall report to the Commission and to the ~~MDCG other Member States~~, at least once a year, on their monitoring activities **regarding their notified bodies and, where applicable, subsidiaries and subcontractors. This report shall provide details of the outcome of the monitoring activities.** This report **shall be treated as confidential by the MDCG and the Commission however it** shall contain a summary which shall be made publicly available.
- The summary report shall be uploaded to the European databank referred to in Article 27.**

## **Article 35a**

### **Review of notified body assessment of technical documentation and clinical evaluation documentation**

- 1. The national authority responsible for notified bodies, as part of its ongoing monitoring of notified bodies shall assess an appropriate number of notified body assessments of manufacturers' technical documentation and clinical evaluations to verify the conclusions drawn by the notified body based on the information presented by the manufacturer. These assessments shall be conducted both off site and during on-site assessments.**
  
- 2. The sample of files assessed in accordance with paragraph 1 shall be planned and representative of the types and risk of devices certified by the notified body and in particular high risk devices, appropriately justified and documented in a sampling plan, which shall be available from the national authority responsible for notified bodies upon request of the MDCG.**
  
- 3. The national authority responsible for notified bodies shall assess whether the assessment by the notified body was conducted appropriately and verify the procedures used, associated documentation and conclusions drawn by the notified body. This shall include the manufacturer's technical and clinical documentation upon which the notified body has based its assessment. These assessments shall be conducted utilising common specifications provided for in Article 7 in the conduct of the assessment.**
  
- 5. These assessments shall also form part of the re-assessment of notified bodies in accordance with Article 35(4) and the joint assessment activities referred to in Article 37(2a). These assessments shall be conducted utilising appropriate expertise.**



6. *The MDCG may, based on the reports of these assessments by the national authority responsible for notified bodies or joint assessment teams, and inputs from the market surveillance and post-market surveillance activities described in Chapter VII, recommend that the sampling, either by the national authority responsible for notified bodies or as part of a joint assessment activity, shall assess a greater or lesser proportion of the clinical evaluations and technical documentation assessed by a notified body.*
7. *The Commission may, by means of implementing acts, adopt measures setting out the modalities, associated documents for and coordination of the technical and clinical assessments referred to in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).*

#### *Article 36*

##### *Changes to **designations and notifications***

1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the ~~notification~~ **designation by the national authority responsible for notified bodies**. The procedures described in Article 32(2) ~~to (6)~~ and in Article 33 shall apply to changes where they entail an extension of the scope of the notification. In all other cases, the Commission shall immediately publish the amended notification in the electronic notification tool referred to in Article 33(10).
  - 1a. *Where a notified body decides to cease its conformity assessment activities it shall inform the national authority responsible for notified bodies and the manufacturers concerned as soon as possible and in case of a planned cessation one year before ceasing its activities. The certificates may remain valid for a temporary period of nine months after cessation of activities on condition that another notified body has confirmed in writing that it will assume responsibilities for these products. The new notified body shall complete a full assessment of the devices affected by the end of that time period before issuing new certificates for those devices.*

2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, 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 notification*, 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. Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.

The national authority responsible for notified bodies shall immediately inform the Commission and the other Member States of any suspension, restriction or withdrawal of a notification.

3. In the event of restriction, suspension or withdrawal of a notification, the Member State shall take appropriate steps to ensure that the files of the notified body concerned are ~~either processed by another notified body or~~ kept available for the national authorities responsible for notified bodies and *national authorities responsible* for market surveillance at their request.

4. The national authority responsible for notified bodies shall:
- assess ~~whether the reasons which gave rise to the change to the notification have an~~ ***the*** impact on the certificates issued by the notified body ***where there is a change to the notification;*** and,
  - ***submit a report on its findings to the Commission and the other Member States*** within three months after having notified the changes to the notification; ~~shall submit a report on its findings to the Commission and the other Member States.~~
  - ***require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued*** ~~Where necessary to ensure the safety of devices on the market; that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.~~
  - ***enter into the electronic system mentioned in Article 45 paragraph 4 all certificates for which it has required suspension or withdrawal;***
  - ***inform the competent authority for medical devices of the Member State where the manufacturer or his authorised representative has his registered place of business through the electronic system referred to in Article 27 of the certificates for which it has required suspension or withdrawal. The competent authority responsible for the manufacturer of the device or his authorised representative shall take the appropriate measures, where necessary to avoid a potential risk to the health or safety of patients, users or others.***

5. ~~The~~ ***With the exception of*** certificates, ~~other than those unduly issued, which were issued by the notified body for which the notification~~ ***and where a designation*** has been suspended; ***or*** restricted, ~~or withdrawn~~ ***the certificates*** shall remain valid in the following circumstances:
- (a) ~~in the case of suspension of a notification: on condition that,~~ ***the national authority responsible for notified bodies has confirmed, within one month of the suspension or restriction, that there is no safety issue for certificates affected by the suspension or restriction;***
- and***
- the national authority responsible for notified bodies has outlined a timeline and actions anticipated to remedy the suspension or restriction;***
- or***
- (b) ***the national authority responsible for notified bodies has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension/restriction and indicates whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction. In case the national authority responsible for notified bodies determines that the notified body does not have the capability to support existing certificates issued, the manufacturer shall provide to the competent authority for devices within three months of the suspension or restriction; either the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate is established, or another notified body confirm in writing the written confirmation that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension; or restriction.***

**5a. With the exception of certificates unduly issued, and where a notification has been withdrawn, the certificates shall remain valid for a period of nine months in the following circumstances:**

- (b) - ~~in the case of restriction or withdrawal of a notification: for a period of three months after the restriction or withdrawal.~~ **Where the competent authority for medical devices of the Member State in which the manufacturer *or the authorised representative* of the device covered by the certificate is established *has confirmed that there is no safety issue associated with the devices in question, and***
- ***another notified body has confirmed in writing that it will assume immediate responsibilities for these products and will have completed assessment of the devices within twelve months from the withdrawal of the notification.***

***Under those circumstances, the national competent authority of the member state where the manufacturer or the authorised representative is established may extend the provisional validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided it is assuming the functions of the notified body during this period.***

~~The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately inform the Commission, the other Member States and the other notified bodies thereof.~~

## Article 37

### *Challenge to the competence of notified bodies*

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 Annex VI or the obligations to which it is subject. ***It shall ensure that the concerned national authority responsible for notified bodies is informed and is given opportunity to investigate these concerns*** ~~It may also commence such investigations on its own initiative.~~
  
2. The notifying Member State shall provide the Commission, on request, with all information regarding the notification of the notified body concerned.
  - 2a. ***The Commission, in conjunction with the MDCG, may initiate, as applicable, the assessment process described in Article 32(3) and (4) when 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 Annex VI and when the investigation of the national authority is not deemed to have fully addressed the concerns or upon request of the national authority. The reporting and outcome of this assessment process shall follow the principles of Article 32. Alternatively, depending on the severity of the issue, the Commission in conjunction with the MDCG may request that the national authority responsible for notified bodies allow for participation of up to two experts from the list established pursuant to Article 32a in an on-site assessment as part of the planned monitoring and surveillance activities in accordance with Article 35 and as outlined in the annual plan described in paragraph 3 therein.***

3. Where the Commission ascertains that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification *designation* if necessary.

Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the notification. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3). It shall notify the Member State concerned of its decision and update the database and list of notified bodies.

- 3a. ***The Commission shall ensure that all confidential information obtained in the course of its investigations is treated confidentially.***

#### *Article 38*

##### *Exchange Peer review and exchange of experience between national authorities responsible for notified bodies*

- I. The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the national authorities responsible for notified bodies under this Regulation. ***This shall address elements including:***
  - (a) ***development of best practice documents relating to the activities of the national authorities responsible for notified bodies;***
  - (b) ***development of guidance documents for notified bodies in relation to the implementation of this Regulation;***
  - (c) ***training and qualification of the experts referred to in Article 32a;***
  - (d) ***monitoring of trends relating to changes to notified body designations and notifications and trends in certificate withdrawals and transfers between notified bodies;***

- (e) monitoring of the application and applicability of scope codes referred to in Article 33(4a);*
  - (f) development of a mechanism for peer reviews between authorities and the Commission;*
  - (g) methods of communication to the public on the monitoring and surveillance activities of authorities and the Commission on notified bodies for medical devices.*
- 2. The national authorities responsible for notified bodies shall participate in a peer review every third year in accordance with the mechanism agreed in Article 38(1). These reviews shall normally be conducted during on-site joint assessments described in Article 32 but alternatively on a voluntary basis may take place as part of the national authority's monitoring activities in Article 35.*
- 3. The Commission shall participate in the organisation and provide support to the implementation of the peer review mechanism, including coordinating the peer reviews components. The Commission shall report on the Member States implementation of the requirements in Article 28, taking best practice in the Union into consideration.*
- 3a. The Commission shall compile a report of the peer review for the national authority being reviewed. The report documenting the outcome of the peer-review shall be communicated to the Member State concerned and, with the consent of the national authority being reviewed, to all other Member States.*
- The Commission shall also compile an annual summary report of the peer review activities which shall be made publicly available.*
- 4. The Commission may, by means of implementing acts, adopt measures setting out the modalities and associated documents for the peer review, training and qualification mechanisms referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).*



## Article 39

### Coordination of notified bodies

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 bodies notified under this Regulation shall participate in the work of that group.

## Article 40

### Fees

1. ~~The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.~~
2. ~~The Commission shall be empowered to adopt delegated acts in accordance with Article 89 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation and cost effectiveness. Particular attention shall be paid to the interests of notified bodies that submitted a valid certificate delivered by the national accreditation body as referred to in Article 31(2) and notified bodies that are small and medium sized enterprises as defined by Commission Recommendation 2003/361/EC.~~

## Chapter V

### Classification and conformity assessment

#### Section 1 – Classification

##### *Article 41*

##### *Classification of medical devices*

1. Devices shall be divided into classes I, IIa, IIb and III, taking into account their ~~intended~~ purpose ***intended by the manufacturer*** and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII.
  
2. Any dispute between the manufacturer and the notified body concerned, arising from the application of the classification criteria, shall be referred for a decision to the competent authority of the Member State where the manufacturer has his 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 where the authorised representative referred to in the last indent of point (b) of Section 3.2. of Annex VIII has his registered place of business. ***Where the notified body concerned is located in a different Member State than the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.***

~~The~~ ***At least 14 days prior to any decision, the competent authority of the manufacturer shall notify the MDCG and the Commission of its envisaged decision.***

3. ~~At The Commission may, at the~~ *a* request of a Member State ~~the Commission shall~~ *or on its own initiative after consulting the MDCG, decide*, by means of implementing acts, ~~decide on~~ the *following*:
- (a) application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification;
  - (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 by way of derogation from the classification criteria set out in Annex VII, be reclassified.*
- 3a. *The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 3, points (a) and (b).*
- 3b. ~~These~~ *The* implementing acts *referred to in paragraphs 3 and 3a* shall be adopted in accordance with the examination procedure referred to in Article 88(3).
4. ~~In order to ensure the uniform application of the classification criteria set out in Annex VII the light of technical progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 61 to 75, the Commission shall be empowered to~~ *may* adopt delegated *implementing* acts in accordance with Article 898(3) as regards the following:
- (a) ~~deciding that a device, or category or group of devices, should, by way of derogation from the classification criteria set out in Annex VII, be classified in another class;~~
  - (b) ~~amending or supplementing the classification criteria set out in Annex VII.~~

## Section 2 – Conformity assessment

### Article 42

#### *Conformity assessment procedures*

1. Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to XI.
  - 1a. Prior to putting into service devices that are not placed on the market, with the exception of devices manufactured pursuant to Article 4(4a), manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to XI.***
2. Manufacturers of devices classified as class III, other than custom-made or investigational devices, shall be subject to a conformity assessment based on full quality ***management system*** assurance and ~~design dossier examination~~ ***assessment of the technical documentation*** as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX coupled with a conformity assessment based on product conformity verification as specified in Annex X.

**2a.** *For implantable devices classified as class III, the notified body shall follow the procedure regarding clinical evaluation consultation as specified in Section 6.0 of Chapter II of annex VIII or Section 6 of Annex IX, as applicable.*

*This procedure is not required where:*

*(a0) in the case of certificate renewal;*

*(a) where the device has been designed by modifications of a device already marketed by the same manufacturer for the same intended purpose if the modifications have been demonstrated by the manufacturer and accepted by the notified body as not adversely affecting significantly the benefit/risk ratio; or*

*(b) where the principles of the clinical evaluation of the device type or category have been addressed in a common specification referred to in Article 7 and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant common specification for clinical evaluation of that kind of device.*

**2b.** *Any notified body that takes a decision in accordance with paragraph 2a shall notify the competent authorities, the national authorities responsible for notified bodies and the Commission accordingly through the system referred to in Article 27. That notification shall be accompanied by the clinical evaluation assessment report.*

**2c.** *The Commission shall by [date 5 year after the date of application of this regulation] draw up a report on the operation of paragraph 2a and submit it to the European Parliament and to the Council. On the basis of this report, the Commission shall, if appropriate, make proposals for amendments to this Regulation.*

**2d.** *In the case of devices referred to in the first subparagraph of Article 1(4), the notified body shall follow the consultation procedure as specified in Section 6.1 of Chapter II of Annex VIII or Section 6 of Annex IX, as applicable.*

- 2e. In the case of devices that are covered by this Regulation in accordance with point (e) *or (ea)* of Article 1(2) *and article 1(5a)*, the notified body shall follow the consultation procedure as specified in Section 6.2 ~~of Chapter II~~ of Annex VIII or Section 6 of Annex IX, as applicable.
3. Manufacturers of devices classified as class IIb, other than custom-made or investigational devices, shall be subject to a conformity assessment based on ~~full~~ quality *management system assurance* as specified in Annex VIII, except for its Chapter II, with assessment of ~~the design documentation within~~ the technical documentation *of at least one* ~~on a representative basis device per generic device group for each category of devices~~. *By way of derogation, the assessment of the technical documentation as specified in Section 5 of Chapter II of Annex VIII shall be applicable for Class IIb implantable devices*. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX coupled with a conformity assessment based on product conformity verification as specified in Annex X.
4. Manufacturers of devices classified as class IIa, other than custom-made or investigational devices, shall be subject to a conformity assessment based on ~~full~~ quality *management system assurance* as specified in Annex VIII, except for its Chapter II, with assessment of ~~the design documentation within~~ the technical documentation *of at least one* ~~on a representative basis device for each category of devices~~. Alternatively, the manufacturer may choose to draw up the technical documentation set out in Annex II coupled with a conformity assessment based on product conformity verification as specified in Section 7 of Part A or Section 8 of Part B of Annex X.

5. Manufacturers of devices classified as class I, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 17 after drawing up the technical documentation set out in Annex II. If the devices are placed on the market in sterile condition or have a measuring function, the manufacturer shall apply the procedures set out in Annex VIII, except for its Chapter II, or in Part A of Annex X. However, **the** involvement of the notified body shall be limited:
- (a) in the case of devices placed on the market in sterile condition, to the aspects of ~~manufacture~~ concerned with **establishing** securing and maintaining sterile conditions,
  - (b) in the case of devices with a measuring function, to the aspects of ~~manufacture~~ concerned with the conformity of the devices with the metrological requirements.
6. ~~Manufacturers may choose to apply a conformity assessment procedure applicable to devices of a higher class than the device in question.~~
7. Manufacturers of custom-made devices shall follow the procedure set out in Annex XI and draw up the statement set out in **Section 1 of** that Annex before placing the device on the market.
- 7a. Manufacturers of class III custom-made implantable devices shall be subject to the conformity assessment procedure based on quality management system as specified in Annex VIII, except for its Chapter II or in Part A of Annex X.**
8. The Member State in which the notified body is established may determine that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 6 shall be available in an official Union language(s) **determined by the Member State concerned**. Otherwise they shall be available in an official Union language acceptable to the notified body.

9. Investigational devices shall be subject to the requirements set out in Articles 50 to 60.
10. The Commission may, by means of implementing acts, specify *or modify* the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects:
- the frequency and the sampling basis of the assessment of ~~the design documentation~~ ~~within~~ the technical documentation on a representative basis as set out in Sections 3.3(c) and 4.5 of Annex VIII in the case of devices of classes IIa and IIb, and in Section 7.2 of Part A of Annex X in the case of devices of class IIa;
  - the minimum frequency of unannounced ~~factory inspections~~ *on-site audits* and sample checks to be conducted by notified bodies in accordance with Section 4.4 of Annex VIII, taking into account the risk-class and the type of device;
  - the physical, laboratory or other tests to be carried out by notified bodies in the context of sample checks, ~~design dossier examination~~ *assessment of the technical documentation* and type examination in accordance with Sections 4.4 and 5.3 of Annex VIII, Section 3 of Annex IX and Section 5 of Part B of Annex X.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

11. In the light of technical *and scientific* progress and any information which becomes available in the course of the designation or monitoring of notified bodies set out in Articles 28 to 40, or of the vigilance and market surveillance activities described in Articles 61 to 75, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the conformity assessment procedures set out in Annexes VIII to XI.



## Article 43

### *Involvement of notified bodies*

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. An application may not be lodged in parallel with ~~more than one~~ **another** notified body for the same conformity assessment activity.
2. The notified body concerned shall inform the other notified bodies of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment, *by means of the electronic system referred to in article 27.*
- 2a. *Manufacturers shall declare whether they have withdrawn an application with another notified body prior to the decision of that notified body and/or provide information about any previous application for the same type that has been refused by another notified body.***
3. The notified body may require any information or data from the manufacturer which is necessary in order to properly conduct the chosen conformity assessment procedure.
4. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities 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.

## Article 44

### *Mechanism for scrutiny of certain conformity assessments*

1. ~~Notified bodies shall notify the Commission of applications for conformity assessments for devices classified as class III, with the exception of applications to supplement or renew existing certificates. A notified body shall notify the national authority responsible for notified bodies competent authorities of certificates it has granted to devices, the conformity assessment of which has been performed pursuant to Article 42(2a).~~ ***Such*** notification shall be accompanied by ~~the draft instructions for use referred to in Section 19.3 of Annex I~~ ***take place automatically through the electronic system referred to in Article 27 and shall include the draft summary of safety and clinical performance information pursuant referred to in Article 26, the assessment report by the notified body, the draft instructions for use referred to in Section 19.3 of Annex I, and, where applicable, the scientific opinion report of the expert panels referred to in Section 6.0 of Chapter II of annex VIII or Section 6 of Annex IX, as applicable, including, where applicable, a justification in case of divergent views between notified body and expert panel. In its notification the notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.***

***A competent authority and, where applicable, the Commission may, based on reasonable concerns, apply further procedures according to articles 35, 35a, 36, 37, 69 and, when deemed necessary, take appropriate measures according to Articles 70 and 73.***

2. ~~Within 28 days of receipt of the information referred to in paragraph 1, the MDCG may request the notified body to submit a summary of the preliminary conformity assessment prior to issuing a certificate. Upon suggestion by any of its members or by the Commission, the MDCG shall decide on making such request in accordance with the procedure set out in Article 78(4). In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file for submission of a summary of the preliminary conformity assessment. When selecting a specific file for submission, the principle of equal treatment shall be duly taken into account.~~

~~Within 5 days after receipt of the request by the MDCG, the notified body shall inform the manufacturer thereof.~~

3. ~~The MDCG may submit comments on the summary of the preliminary conformity assessment at the latest 60 days after submission of this summary. Within that period and at the latest 30 days after submission, the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this subparagraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.~~
4. ~~The notified body shall give due consideration to any comments received in accordance with paragraph 3. It shall convey to the Commission an explanation of how they have been taken into consideration, including any due justification for not following the comments received, and its final decision regarding the conformity assessment in question. The Commission shall immediately transmit this information to the MDCG.~~

5. ~~Where deemed necessary for the protection of patient safety and public health, the Commission, may determine, by means of implementing acts, specific categories or groups of devices, other than devices of class III, to which paragraphs 1 to 4 shall apply during a predefined period of time. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).~~

~~Measures pursuant to this paragraph may be justified only by one or more of the following criteria:~~

- ~~(a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof;~~
- ~~(b) an adverse change in the risk benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;~~
- ~~(c) an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices;~~
- ~~(d) significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices;~~
- ~~(e) public health concerns regarding a specific category or group of devices or the technology on which they are based.~~

6. ~~The Commission shall make a summary of the comments submitted in accordance with paragraph 3 and the outcome of the conformity assessment procedure accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.~~

7. ~~The Commission shall set up the technical infrastructure for the data exchange by an electronic means between notified bodies and MDCG for the purposes of this Article.~~

8. ~~The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the summary of the preliminary conformity assessment in accordance with paragraphs 2 and 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).~~

*Article 45*

*Certificates*

1. The certificates issued by the notified bodies in accordance with Annexes VIII, IX and X shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates is set out in Annex XII.
  2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.
- 2a. Notified bodies may impose restrictions to the intended purpose of a device to certain groups of patients or require manufacturers to undertake specific post-market clinical follow-up studies pursuant to Part B of Annex XIII.***
3. Where a notified body finds that 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 restrictions 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. The notified body shall give the reasons for its decision.

4. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on certificates issued by notified bodies. The notified body shall enter into this electronic system information regarding certificates issued, including amendments and supplements, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. This information shall be accessible to the public.
5. In the light of technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the minimum content of the certificates set out in Annex XII.

#### *Article 46*

##### *Voluntary change of notified body*

1. In cases where a manufacturer terminates his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, ***where practicable*** the outgoing notified body and the incoming notified body. This agreement shall address at least the following aspects:
  - (a) the date of invalidity of certificates issued by the outgoing notified body;
  - (b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;
  - (c) the transfer of documents, including confidentiality aspects and property rights;
  - ~~(d) the date as of which the incoming notified body assumes full responsibility for the conformity assessment tasks.~~
  - (e) ***the date after which the conformity assessment tasks of the outgoing Notified Body is assigned to the incoming notified body;***
  - (f) ***the last serial number or batch number for which the outgoing notified body is responsible.***

2. On their date of invalidity, the outgoing notified body shall withdraw the certificates it has issued for the device concerned.

#### *Article 47*

##### *Derogation from the conformity assessment procedures*

1. By way of derogation from Article 42, any competent authority may authorise, on duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific device for which the procedures referred to in Article 42 have not been carried out and use of which is in the interest of public health or patient safety *or health*.
2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.
3. ~~Upon request by a Member State and where this is in the interest of~~ ***Following a notification pursuant to paragraph 2, the Commission, in exceptional cases relating to*** public health or patient safety ***or health, in more than one Member State, the Commission*** may, by means of implementing acts, extend for a determined period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(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 88(4).

## Article 48

### *Certificate of free sale*

1. For the purpose of export and upon request by a manufacturer *or an authorised representative*, the Member State in which the manufacturer *or the authorised representative* has its registered place of business shall issue a certificate of free sale declaring that the manufacturer *or the authorised representative, as applicable*, is properly established and that the device in question bearing the CE-marking in accordance with this Regulation may be legally marketed in the Union. The certificate of free sale shall be valid for the period indicated on it which shall not exceed five years and shall not exceed the validity of the *set out the identification of the device in the electronic system set up under Article 24b. Where a notified body has issued a certificate referred to in Article 45, the certificate of free sale shall set out the identification unique number identifying that certificate, pursuant to section 3, Chapter II of Annex XII of the certificate referred to in Article 45* issued for the device in question.
2. The Commission may, by means of implementing acts, establish a model for certificates of free sale taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).



# Chapter VI

## Clinical evaluation and clinical investigations

### Article 49

#### Clinical evaluation

1. **Confirmation of conformity with the general safety and performance requirements concerning the characteristics of safety and performances referred to in Annex I and where applicable relevant requirements of Annex IIa under the normal conditions of the intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on clinical data providing sufficient clinical evidence.**

*The manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate compliance with the relevant essential requirements on safety and performance which shall be appropriate to the characteristics of the device and its intended purpose.*

~~Manufacturers~~ *To that end, manufacturers shall plan, conduct and document a clinical evaluation in accordance with the principles set out in this Article and Part A of Annex XIII.*

- 1a. *For devices classified as class III and following the exemptions for the procedure laid down in article 42(2a), the manufacturer may, prior to its clinical evaluation and/or investigation, consult an expert panel according to the procedure mentioned in article 81a, with the aim to review the manufacturer's intended clinical ~~evaluation~~ development strategy and proposals for clinical investigation(s). The manufacturer shall give due consideration to the views expressed by the expert panel. These considerations shall be documented in the clinical evaluation report referred to in paragraph 5.*

*The manufacturer ~~cannot~~ may not evoke any rights to the views expressed by the expert panel with regard to any future conformity assessment procedure.*

2. A clinical evaluation shall follow a defined and methodologically sound procedure based on ~~either of~~ the following:
- (a) a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where the following conditions are satisfied:
    - it is demonstrated that the device ~~and its intended use~~ subject to clinical evaluation ***for the intended use is equivalent to*** ~~and~~ the device to which the data relate, ~~are equivalent~~ ***in accordance with Section 4a of Part A of Annex XIII,***  
***and***
    - the data adequately demonstrate compliance with the relevant general safety and performance requirements;
  - (b) a critical evaluation of the results of all clinical investigations, ***having due regard to whether the investigations were*** performed in accordance with Articles 50 to 60 and Annex XIV;
  - (c) ~~a critical evaluation of the combined clinical data referred to in points (a) and (b).~~
  - (d) ***a consideration of currently available alternative treatment options for that purpose, if any.***

**2a. In the case of implantable devices and devices falling within class III, clinical investigations shall be performed, except if:**

- **the device has been designed by modifications of a device already marketed by the same manufacturer;**
- **if the modified device ~~modifications~~ has been scientifically demonstrated by the manufacturer to be equivalent to the marketed device, in accordance with Section 4a of Part A of Annex XIII and this demonstration has been ~~accepted~~ endorsed by the notified body as ~~being equivalent in accordance to Section A Annex XIII, to the marketed device~~ ;**

**and**

- **the clinical ~~evaluation~~ investigation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.**

**In this case the notified body shall check that the PMCF plan is appropriate and includes post market studies to demonstrate the safety and performance of the device.**

**With regard to the first subparagraph, a manufacturer ~~can~~ may seek to justify use of data from a demonstrated equivalent device from another manufacturer only if they have a clear contract in place with that manufacturer allowing full access to the technical documentation on an ongoing basis. The manufacturer must be able to provide clear evidence of this to the notified body, ~~of the nature of any modification~~ and also evidence that the original clinical investigations have been performed in compliance with the requirements of this Regulation. In addition, the manufacturer must be able to provide a description of the nature of any modification.**

3. ~~Where~~ ***Except for class III and implantable devices, where*** demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception 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 performances intended and the claims of the manufacturer. The adequacy of demonstration of conformity with the general safety and performance requirements based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, has to be duly substantiated in the technical documentation referred to in Annex II.
4. The clinical evaluation and its documentation shall be updated throughout the life cycle of the device concerned with ***clinical*** data obtained from the implementation of the manufacturer's ***PMCF according to Annex XIII Part B and the*** post-market surveillance plan referred to in Article ~~60ba~~ ~~8(6 7)~~.

***For devices classified as class III and implantable devices, the PMCF report and, if indicated, the summary of safety and clinical performance referred to in Article 26(1) shall be updated at least annually with these data.***

5. The clinical evaluation, ***its results*** and ~~its outcome~~ ***the clinical evidence derived from it*** shall be documented in a clinical evaluation report referred to in Section 6 of Part A of Annex XIII, which, ***except for custom-made devices***, shall be ~~included or fully referenced in part of~~ the technical documentation referred to in Annex II relating to the device concerned.
6. ***Where necessary to ensure the uniform application of Annex XIII, the Commission may, having due regard to technical and scientific progress, adopt implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).***

## Article 50

### *General requirements regarding clinical investigations ~~conducted to ensure~~ establish conformity of devices*

1. Clinical investigations shall be ~~subject to~~ ***designed, authorized, conducted, recorded and reported in accordance with the provisions of*** Articles 50-60 and Annex XIV if they are ~~conducted~~ ***carried out as part of the clinical evaluation for conformity assessment purposes*** for one or more of the following purposes:
  - (a) to ~~establish and~~ verify that, under normal conditions of use, ***a device is*** ~~devices are~~ designed, manufactured and packaged in such a way that ~~they are~~ ***it is*** suitable for one or more of the specific purposes of a medical device referred to in number (1) of Article 2(1), and achieve the performances intended as specified by ~~the sponsor its~~ manufacturer;
  - (b) to ~~establish and~~ verify that devices achieve the intended ***clinical*** benefits ~~of the a device for to the patient~~ ***subject*** as specified by ~~the sponsor its~~ manufacturer;
  - (c) to determine any undesirable side-effects, under normal conditions of use ***of a device***, and assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the device.
  
2. Where the sponsor ***of a clinical investigation*** is not established in the Union, ~~he~~ ***that sponsor*** shall ensure that a ~~contact~~ ***natural or legal*** person is established in the Union ***as its legal representative***. ~~That contact person~~ ***Such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to this Regulation, and*** shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication to that ~~contact person~~ ***legal representative*** shall be ***deemed to be a*** ~~considered~~ as communication to the sponsor.

***Member States may choose not to apply the subparagraph above as regards clinical investigations to be conducted solely on their territory, or on their territory and the territory of a third country, provided that they ensure that the sponsor establishes at least a contact person on their territory in respect of that clinical investigation who shall be the addressee for all communications with the sponsor provided for in this Regulation.***

3. Clinical investigations shall be designed and conducted in a way that the rights, safety, *dignity* and well-being of the subjects participating in a clinical investigation are protected and *prevail over all other interests and* that the clinical data generated ~~in the clinical investigation~~ are going to be *scientifically valid*, reliable and robust.

*Clinical investigations shall be subject to scientific and ethical review. The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. Member States shall ensure that the ~~timelines and~~ procedures for the review by the ethics committees are compatible with the ~~timelines and~~ procedures set out in this Regulation for the assessment of the application for authorisation of a clinical investigation.*

4. ~~Clinical investigations shall be designed, conducted, recorded and reported in accordance with the provisions of Articles 50 to 60 and of Annex XIV.~~

5. *A clinical investigation according to paragraph 1 may be conducted only where all of the following conditions are met:*
- (a) the clinical investigation was subject to an authorisation by a Member State(s) concerned, in accordance with this Regulation, unless otherwise stated,*
  - (b) ~~where appropriate,~~ an independent ethics committee, set up according to national law, has issued an opinion on the planned clinical investigation which is not negative and which, in accordance with the law of the Member State concerned, is valid for that entire Member State;*
  - (c) the sponsor, or its legal representative or a contact person pursuant to paragraph 2, is established in the Union;*
  - (cb) vulnerable populations and subjects are appropriately protected according to relevant national provisions;*
  - (d) the foreseeable risks and inconveniences to the subject are medically justifiable when weighed against the device's potential relevance for the subjects ~~and/or medicine~~;*
  - (e) the subject or, where the subject is not able to give informed consent, his or her legally designated representative has given informed consent in accordance with Article 29 of Regulation (EU) No 536/2014;*
  - (h) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him or her in accordance with Directive 95/46/EC are safeguarded;*
  - (l) the investigational device(s) in question conform(s) to the applicable general safety and performance requirements apart from the aspects covered by the clinical investigation and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, where appropriate, technical and biological safety testing and pre-clinical evaluation, as well as provisions in the field of occupational safety and accident prevention, taking into consideration the state of the art.*
  - (m) the requirements of Annex XIV are fulfilled.*

*Any subject may, without any resulting detriment, withdraw from the clinical investigation at any time by revoking his or her informed consent. Without prejudice to Directive 95/46/EC, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal.*

8. *The investigator shall be a person, ~~as defined in national law~~, following a profession which is recognised in the Member State concerned as qualifying for an investigator because of the necessary scientific knowledge and experience in patient care. Other individuals involved in conducting a clinical investigation shall be suitably qualified by education, training or experience in the relevant medical field and in clinical research methodology, to perform their tasks.*
9. *The facilities where the clinical investigation is to be conducted shall be similar to the facilities of the intended use and suitable for the clinical investigation.*

#### *Article 50c*

##### *Protection of vulnerable subjects, emergency situations*

*In order to specifically protect the rights, safety, dignity and well-being of vulnerable subjects in clinical investigations, Member States shall take appropriate measures, concerning clinical investigations*

- (a) *on minors,*
- (b) *on incapacitated subjects,*
- (c) *on pregnant and breastfeeding women,*
- (d) *in emergency situations, and/or*
- (e) *on persons in residential care institutions, persons performing mandatory military service, persons deprived of liberty, persons who, due to a judicial decision, cannot take part in clinical investigations.*

#### *Article 50d*

##### *Damage compensation*

1. *Member States shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a clinical investigation conducted on their territory are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk.*



2. *The sponsor and the investigator shall make use of the system referred to in paragraph 1 in the form appropriate for the Member State concerned where the clinical investigation is conducted.*

#### *Article 51*

##### *Application for clinical investigations*

1. ~~Before making the first application, the sponsor shall procure from the electronic system referred to in Article 53 a single identification number for a clinical investigation conducted in one site or multiple sites, in one or more than one Member State. The sponsor shall use this single identification number when registering the clinical investigation in accordance with Article 52.~~
2. The sponsor of a clinical investigation shall ~~enter and~~ submit *by means of the electronic system referred to in Article 53* an application to the Member State(s) in which the investigation is to be conducted accompanied by the documentation referred to in Chapter II of Annex XIV. *The electronic system referred to in Article 53 shall generate a Union-wide unique single identification number for this clinical investigation which shall be used for all relevant communication in relation to the clinical investigation concerned.* Within ~~six~~ *ten* days after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical investigation falls within the scope of this Regulation and whether the application is complete.

~~Where the Member State has not notified the sponsor within the time period referred to in the first subparagraph, the clinical investigation shall be considered as falling within the scope of this Regulation and the application shall be considered complete.~~

3. Where the Member State finds that the clinical investigation applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of ~~six~~ **thirty** days for the sponsor to comment or to complete the application.

Where the sponsor has not provided comments nor completed the application within the time-period referred to in the first subparagraph, the application shall be *deemed to have lapsed* ~~considered as withdrawn~~. *Where the sponsor considers the application does fall under the scope of the regulation and/or is complete but the competent authority does not, the application shall be considered as rejected. That Member State shall provide for an appeal procedure in respect of such refusal.*

~~Where~~ ~~†~~ The Member State has ~~not to notify~~ notified the sponsor according to paragraph 2 within ~~three~~ **five** days following receipt of the comments or of the *requested additional information* ~~completed application~~, *whether* the clinical investigation ~~shall be~~ *is* considered as falling within the scope of this Regulation and the application ~~shall be considered~~ *is* completed.

4. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraph 2 *or* 3 shall be the validation date of the application. ~~Where the sponsor is not notified, the validation date shall be the last day of the time periods referred to in paragraphs 2 and 3.~~ *The concerned Member State may also extend the period referred to in paragraph 2 and 3 each by a further 5 days.*
  - 4a. *In the period during which the application is being assessed the Member State may request, additional information from the sponsor. The expiry of the deadline pursuant paragraph 5(b) (second indent) shall be suspended from the date of the first request until such time as the additional information has been received.*

5. The sponsor may start the clinical investigation in the following circumstances:
- (a) in the case of investigational devices classified as class **I III** ~~and implantable or long-term~~ **or in the case of non-invasive** devices classified as class IIa or IIb, ~~as soon as the Member State concerned has notified the sponsor of its approval~~ **unless otherwise stated by national provisions, immediately after the validation date of the application described in paragraph 4, and provided where appropriate that the competent ethics committee in the Member State concerned has issued an opinion which is not negative and which, in accordance with the law of the Member State concerned, is valid for that entire Member State;**
  - (b) in the case of investigational devices other than those referred to in point (a):
    - **as soon as the Member State concerned has notified the sponsor of its authorisation and provided where appropriate that the competent ethics committee in the Member State concerned has issued an opinion which is not negative and which, in accordance with the law of the Member State concerned, is valid for that entire Member State or**
    - **after the expiry of 45 days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal and provided that the ethics committee in the Member State concerned has issued an opinion which is not negative and which, in accordance with the law of the Member State concerned, is valid for that entire Member State.**

***The Member State concerned may also extend the period referred to in the previous sub-paragraph by a further 20 days for the purpose of consulting with experts. immediately after the date of application provided that the Member State concerned has so decided and that evidence is provided that the rights, safety and well-being of the subjects to the clinical investigation are protected;***
  - (c) ~~after the expiry of 35 days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.~~

6. ~~Member States shall ensure that the persons assessing the application do not have conflicts of interest and that they are independent of the sponsor, the institution of the investigation site(s) and the investigators involved, as well as free of any other undue influence.~~

~~Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of at least one person whose primary area of interest is non-scientific shall be taken into account. The view of at least one patient shall be taken into account.~~

7. The Commission ~~shall be empowered to~~ *may* adopt delegated *implementing* acts in accordance with Article 89 ~~88(3)~~ amending or supplementing, in the light of technical progress and global regulatory developments, *in order to assure the uniform application of* the requirements for the documentation to be submitted with the application for the clinical investigation that is laid down in Chapter II of Annex XIV.

#### *Article 51a*

##### *Assessment by Member States*

1. *Member States shall ensure that the persons validating and assessing the application, or deciding on it, do not have conflicts of interest, are independent of the sponsor, the investigators involved and of persons or legal persons financing the clinical investigation, as well as free of any other undue influence.*
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.*

3. *Member States shall assess whether the clinical investigation is designed in such a way that potential remaining risks to subjects or third person, after risk minimization, are justified, when weighed against the clinical benefits to be expected. They shall examine, under consideration of applicable common specifications or harmonized standards, in particular:*
- (a) the demonstration of compliance of the investigational device(s) with the applicable general safety and performance requirements, apart from the aspects covered by the clinical investigation and whether, with regard to these aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, where appropriate, assurance of technical and biological safety testing and pre-clinical evaluation;*
  - (b) whether the risk-minimisation solutions employed by the sponsor are described in harmonised standards and, in those cases where the sponsor does not use harmonised standards, the equivalence of the level of protection to harmonised standards;*
  - (c) the plausibility of the measures planned for the safe installation, putting into service and maintenance of the investigational device;*
  - (d) the reliability and robustness of the data generated in the clinical investigation, taking account of statistical approaches, design of the investigation and methodological aspects (including sample size, comparator and endpoints);*
  - (da) the requirements of Annex XIV are met.*
  - (e) in the case of devices for sterile use, evidence of the validation of the manufacturer's sterilisation procedures or information on the reconditioning and sterilisation procedures which must be conducted by the investigation site;*
  - (f) demonstration of safety, quality and usefulness of any components of animal or human origin or of substances, which may be considered medicinal products according to Directive 2001/83/EC.*

4. *Member States may refuse the authorisation of the clinical investigation if:*
- (a) the clinical investigation does not fall within the scope of this Regulation ;*
  - (b) the application submitted according to Article 51 paragraph 2 remains incomplete;*
  - (c) ~~where appropriate~~ an ethics committee has issued a negative opinion which, in accordance with the law of the Member State concerned, is valid for that entire Member State;*
  - (ca) the device or the submitted documents, especially the investigation plan and the investigator's brochure, do not correspond to the state of scientific knowledge, and the clinical investigation, in particular, is not suitable to provide evidence for the safety, performance characteristics or benefit of the device on-subjects patients, or*
  - (d) the requirements of Article 50 are not met, or*
  - (e) any assessment according to paragraph 3 is negative.*

#### *Article 51e*

##### *Conduct of a clinical investigation*

- 1. The sponsor and the investigator shall ensure that the clinical investigation is conducted in accordance with the approved clinical investigation plan.*
- 2. In order to verify that the rights, safety and well-being of subjects are protected, that the reported data are reliable and robust, and that the conduct of the clinical investigation is in compliance with the requirements of this Regulation, the sponsor shall adequately monitor the conduct of a clinical investigation. The extent and nature of the monitoring shall be determined by the sponsor on the basis of an assessment that takes into consideration all characteristics of the clinical investigation including the following characteristics:*
  - (a) the objective and methodology of the clinical investigation and*
  - (b) the degree of deviation of the intervention from normal clinical practice.*

3. *All clinical investigation information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.*
4. *Appropriate technical and organisational measures shall be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves the transmission over a network.*
5. *Member States shall inspect on an appropriate level investigation site(s) to check that clinical investigations are conducted according to the requirements of this Regulation and to the approved investigation plan.*
6. *The sponsor shall establish a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the investigation.*

#### *Article 52*

##### *Registration of clinical investigations*

1. ~~Before commencing the clinical investigation, the sponsor shall enter in the electronic system referred to in Article 53 the following information regarding the clinical investigation:~~
  - ~~(a) the single identification number of the clinical investigation;~~
  - ~~(b) the name and contact details of the sponsor and, if applicable, his contact person established in the Union;~~
  - ~~(c) the name and contact details of the natural or legal person responsible for the manufacture of the investigational device, if different from the sponsor;~~
  - ~~(d) the description of the investigational device;~~
  - ~~(e) the description of the comparator(s), if applicable;~~
  - ~~(f) the purpose of the clinical investigation;~~
  - ~~(g) the status of the clinical investigation.~~

2. ~~Within one week of any change occurring in relation to the information referred to in paragraph 1, the sponsor shall update the relevant data in the electronic system referred to in Article 53.~~
  
3. ~~The information shall be accessible to the public, through the electronic system referred to in Article 53, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:~~
  - (a) ~~protection of personal data in accordance with Regulation (EC) No 45/2001;~~
  - (b) ~~protection of commercially sensitive information;~~
  - (c) ~~effective supervision of the conduct of the clinical investigation by the Member State(s) concerned.~~
  
4. ~~No personal data of subjects participating in clinical investigations shall be publicly available.~~



## Article 53

### *Electronic system on clinical investigations*

1. The Commission shall, in collaboration with the Member States, set up, ~~and manage~~ **and maintain** an electronic system:
  - (*aa*) to create the single identification numbers for clinical investigations; ~~referred to in Article 51(1) and to collate and process the following information:~~
    - (a) ~~the registration of clinical investigations in accordance with Article 512;~~
    - (*ab*) **to be used as an entry point for the submission of all applications for clinical investigations referred to in Articles 51( 2), 54,, 55 and 58 and for all other submission of data, or processing of data in this context;**
    - (b) **for the exchange of information relating to clinical investigations in accordance with this Regulation** between the Member States and between them and the Commission ~~in accordance with~~ **including those according to Article 51a and 56;**
    - (*ba*) **for information by the sponsor in accordance with Article 57;**
    - (c) ~~the information related to clinical investigations conducted in more than one Member State in case of a single application in accordance with Article 58;~~
    - (d) **for reporting** reports on serious adverse events and device deficiencies **and related updates** referred to in Article 59(2) ~~in case of a single application in accordance with Article 58.;~~
    - (e) **for collecting the clinical investigation reports and the summaries thereof.**
2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article [...] of Regulation (EU) No [536/2014] **as concerns combined clinical investigations of devices with a clinical trial under that regulation.** ~~With the exception of the information referred to in Article 52, the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission.~~

- 2a. Within one week of any change occurring in relation to the information referred to in paragraph 1 or in Article 51(2), the sponsor shall update the relevant data in the electronic system referred to in this Article. The Member State concerned shall be notified of the update and the changes to the documents shall be clearly identifiable.*
- 2b. The information referred to in paragraph 1 except the information referred to in point b, which shall only be accessible to the Member States and the Commission, shall be accessible to the public, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:*
- (a) protection of personal data in accordance with Regulation (EC) No 45/2001;*
  - (b) protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of the conformity assessment for the device, unless there is an overriding public interest in disclosure,*
  - (c) effective supervision of the conduct of the clinical investigation by the Member State(s) concerned;*
- 2ba. No personal data of subjects participating in clinical investigations shall be publicly available.*
- 2c. The user interface of the electronic system referred to in this Article shall be available in all official languages of the Union.*
- ~~3. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 determining which other information regarding clinical investigations collated and processed in the electronic system shall be publicly accessible to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No [... /]. Article 52(3) and (4) shall apply.~~

## Article 54

### *Clinical investigations with devices authorised to bear the CE marking*

1. Where a clinical investigation is to be conducted to further assess a device which is authorised in accordance with Article 42 to bear the CE marking and within its intended purpose referred to in the relevant conformity assessment procedure, hereinafter referred to as ‘post-market clinical follow-up investigation’, the sponsor shall notify the Member States concerned at least 30 days prior to their commencement if the investigation would submit subjects to additionally invasive or burdensome procedures. ***The notification shall be made by means of the electronic system referred to in Article 53. It shall be accompanied by the documentation referred to in Chapter II of Annex XIV. Article 50 paragraph 5 points (b) to (h) and (m), Article 50(1) to (3), Article 52, Article 55, Article 56(1), Article 57(1), the first subparagraph of Article 57(2), Article 59(6) and the relevant provisions of Annex XIV shall apply.***
2. If the aim of the clinical investigation regarding a device which is authorised in accordance with Article 42 to bear the CE marking is to assess such device for a purpose other than that referred to in the information supplied by the manufacturer in accordance with Section 19 of Annex I and in the relevant conformity assessment procedure, Articles 50 to 60 shall apply.

## Article 55

### *Substantial modifications to a clinical investigation*

1. If the sponsor ~~introduces~~ ***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, he shall notify ***by means of the electronic system referred to in Article 53*** the Member State(s) concerned of the reasons for and the content of those modifications. The notification shall be accompanied by an updated version of the relevant documentation referred to in Chapter II of Annex XIV, ***changes shall be clearly identifiable.***

2. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 380 days after notification, unless the Member State concerned has notified the sponsor of its refusal based on *Article 51a paragraph 4 or* considerations of public health, ~~patient~~ *subject and user safety or health*, ~~or~~ of public policy, ~~or where appropriate the ethics committee has issued a negative opinion which in accordance with the law of that Member State, is valid for that entire Member State.~~
3. *The Member State(s) concerned may extend the period referred to in paragraph 2 by a further 7 days, for the purpose of consulting with experts.*

#### *Article 56*

#### *Corrective measures to be taken by Member States and Information exchange between Member States*

- 0a. *Where a Member State concerned has grounds for considering that the requirements set out in this Regulation are no longer met, it may at least take the following measures on its territory:*
  - (a) *withdraw or revoke the authorisation of a clinical investigation;*
  - (b) *suspend, temporary halt or terminate a clinical investigation;*
  - (c) *require the sponsor to modify any aspect of the clinical investigation.*
- 0b. *Before the Member State concerned takes any of the measures referred to in paragraph 0a it shall, except where immediate action is required, ask the sponsor and/or the investigator for their opinion. That opinion shall be delivered within seven days.*
1. Where a Member State *has taken a measure referred to in paragraph 0a or* has refused, ~~suspended or terminated a clinical investigation, or has called for a substantial modification or temporary halt of a clinical investigation,~~ or has been notified by the sponsor of the early termination of a clinical investigation on safety grounds, that Member State shall communicate ~~its~~ *this* decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 53.

2. Where application is withdrawn by the sponsor prior to a decision by a Member State, that ~~Member State shall inform~~ **information shall be available to** all the other Member States and the Commission ~~of that fact~~, by means of the electronic system referred to in Article 53.

#### Article 57

##### *Information by the sponsor in the event of temporary halt or termination of a clinical investigation*

1. If the sponsor has temporarily halted a clinical investigation ~~on safety grounds or has~~ **terminated a clinical investigation early**, he shall inform the Member States concerned within 15 days~~s~~, of the temporary halt **or early termination, providing a justification. In case the sponsor has temporary halted or early terminated the clinical investigation on safety grounds, he shall inform the Member states concerned thereof within 24 hours.**
2. The sponsor shall notify each Member State concerned of the end of a clinical investigation in relation to that Member State, ~~providing a justification in the event of early termination~~. That notification shall be made within 15 days from the end of the clinical investigation in relation to that Member State.
  - 2a. If the investigation is conducted in more than one Member State the sponsor shall notify all Member States concerned of the overall end of the clinical investigation. That notification shall be made within 15 days from the overall end of the clinical investigation.
3. Within one year from the end of the clinical investigation **or within three months from the early termination**, the sponsor shall submit to the Member States concerned **through the electronic system referred to in Article 53** ~~a summary of the results of the clinical investigation in form of a clinical investigation report referred to in Section 2.7 of Chapter I of Annex XIV. Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year~~ **after the completion of the investigation**, it shall be submitted as soon as it is available. In this case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XIV shall specify when the results of the clinical investigation are going to be submitted, together with an explanation.

4. *A summary of the clinical investigation report shall be provided by the sponsor at least the latest within 1 year following the provision of the clinical investigation report according to paragraph 3. The summary of the clinical investigation report shall be written in a way that is readily understood by the intended user of the device.*
  
5. *Submission of information and reports according to paragraphs 1 to 4 shall be accomplished through the electronic system referred to in Article 53. The reports according to paragraphs 3 and 4 shall become publicly accessible through the electronic system, at the latest when the device is CE-marked and before it is placed on the market.*

#### *Article 58*

##### *Clinical investigations conducted in more than one Member State*

1. By means of the electronic system referred to in Article 53, the sponsor of a clinical investigation to be conducted in more than one Member State may submit, for the purpose of Article 51, a single application that, upon receipt, is transmitted electronically to the Member States concerned, *who have voluntarily agreed to that procedure concerning that clinical investigation.*
  
2. In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. ~~If that Member State does not wish to be the coordinating Member State, it~~ *Concerned Member States* shall agree, within six days of submission of the single application, ~~with another Member State concerned that the latter shall be~~ *agree on one of them taking the role of* the coordinating Member State. ~~If no other Member State accepts to be the~~ *If they do not agree on a* coordinating Member State, the ~~Member State~~ *one* proposed by the sponsor shall ~~be the coordinating Member State~~ *take that role*. If another Member State than the one proposed by the sponsor becomes coordinating Member State, ~~the~~ *The* deadlines referred to in Article 51(2) shall start on the day following the *notification of the coordinating Member State to the sponsor (notification date)* acceptance.

3. Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation submitted in accordance with Chapter II of Annex XIV, except for Sections **1.13**, 3.1.3, 4.2, 4.3 and 4.4 thereof which shall be assessed separately by each Member State concerned.

The coordinating Member State shall:

- (a) within 6 days of receipt of the single application notify the sponsor ***that it is the coordinating Member State (notification date)***;
- (aa) ***within 10 days of the notification date ~~single application~~, notify the sponsor*** whether the clinical investigation falls within the scope of this Regulation and whether the application is complete, except for the documentation submitted in accordance with Sections **1.13**, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV for which each Member State shall verify the completeness ***and notify the sponsor accordingly***. Article 51(2) to (4) shall apply to the coordinating Member State in relation to the verification that the clinical investigation falls within the scope of this Regulation and that the application is complete, ***having taken into account considerations expressed by the other Member States concerned***, except for the documentation submitted in accordance with Sections **1.13**, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV. ***for which each Member State shall verify the completeness. Concerned Member States may communicate to the coordinating Member State any considerations relevant to the validation of the application within seven days from the notification date.*** Article 51(2) to (4) shall apply to ~~***the coordinating***~~ each Member State in relation to the verification that the ~~***clinical investigation falls within the scope of this Regulation and that the application is complete, except for the***~~ documentation submitted in accordance with Sections **1.13**, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV is complete;

- (b) establish the results of ~~the coordinated~~ *its* assessment in a *draft assessment* report to be *transmitted within 26 days after the validation date to the concerned Member States. Until day 38 after the validation date the other concerned Member States shall transmit their comments and proposals on the draft assessment report and the underlying application to the coordinating Member State, which shall take due account of it in the finalization of the final assessment report, to be transmitted within 45 days following the validation date to the sponsor and the concerned Member States. The final assessment report shall be taken into account by the other Member States concerned when deciding on the sponsor's application in accordance with Article 51(5), except for Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV, which shall be assessed separately by each Member State concerned.*

*As concerns the assessment of the documentation related to Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV, done separately by each Member State, the Member State may request, on a single occasion, additional information from the sponsor. The expiry of the deadline pursuant to paragraph 3(b) shall be suspended from the date of the request until such time as the additional information has been received.*

- 3a. *The coordinating Member State may also extend the periods referred to in paragraph 3 by a further 50 days, for the purpose of consulting with experts. In such case, the periods referred to in paragraphs 3 of this Article shall apply mutatis mutandis.*



**3b. The Commission may, by means of implementing acts, set out the procedures and timescales for a coordinated assessment led by the coordinating Member State, that shall be taken into account by concerned Member States when deciding on the sponsor's application. Such implementing acts may also cover the procedures for coordinated assessment in the case of substantial modifications pursuant to paragraph 4 and in the case of reporting of events pursuant to Article 59(4) or in the case of clinical investigations of combination products between medical devices and medicinal products, where the latter are under a concurrent coordinated assessment of a clinical trial under Regulation (EU) No 536/2014. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).**

**3c. Where the conclusion of the coordinating Member State is that the conduct of the clinical investigation is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the Member State(s) concerned.**

**Notwithstanding the previous subparagraph, a Member State concerned may disagree with the conclusion of the coordinating Member State concerning the area of joint assessment only on the following grounds:**

- (a) when it considers that participation in the clinical investigation would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned;**
- (b) infringement of national law;**
- (c) considerations as regards subject safety and data reliability and robustness submitted under paragraph 3 point (c).**

**Where a Member State concerned disagrees with the conclusion, it shall communicate its disagreement, together with a detailed justification, through the electronic system referred to in Article 53, to the Commission, to all Member States concerned and to the sponsor.**

- 3d. A Member State concerned shall refuse to authorise a clinical investigation if it disagrees with the conclusion of the coordinating Member State as regards any of the grounds referred to in the second subparagraph of paragraph 3c, or if it finds, on duly justified grounds, that the aspects addressed in Sections 1.13., 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV are not complied with, or ~~where appropriate~~ where an ethics committee has issued a negative opinion which in accordance with the law of the Member State concerned is valid for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.*
- 3da. Each Member State concerned shall notify the sponsor through the electronic system referred to in Article 53 as to whether the clinical investigation is authorised, whether it is authorised subject to conditions, or whether authorisation is refused. Notification shall be done by way of one single decision within five days from the reporting date. An authorisation of a clinical investigation subject to conditions is restricted to conditions which by their nature cannot be fulfilled at the time of that authorisation.*
- 3e. Where the conclusion of the coordinating Member State report is that the clinical investigation is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.*
4. The substantial modifications *as* referred to in Article 55 shall be notified to the Member States concerned by means of the electronic system referred to in Article 53. Any assessment as to whether there are grounds for refusal as referred to in ~~Article 55~~ **paragraph 3c** shall be carried out under the direction of the coordinating Member State, **except for substantial modifications concerning Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XIV, which shall be assessed by each concerned Member State on its own.**
5. For the purpose of Article 57(3), the sponsor shall submit the clinical investigation report to the Member States concerned by means of the electronic system referred to in Article 53.

6. The Commission shall provide ~~secretarial~~ **administrative** support to the coordinating Member State in the accomplishment of its tasks provided for in this Chapter.

#### *Article 58a*

##### *Review of clinical investigations rules*

*Five years after the date referred to in the first paragraph of Article 97, the Commission shall make a report on the application of Article 58 of the present Regulation and propose a review of the provision of Article 58 in order to ensure a coordinated assessment procedure of clinical investigations conducted in more than one Member State.*

#### *Article 59*

##### *Recording and reporting of events occurring during clinical investigations*

1. The sponsor shall fully record any of the following:
  - (a) an adverse event identified in the clinical investigation plan as critical to the evaluation of the results of the clinical investigation in view of the purposes referred to in Article 50(1);
  - (b) a serious adverse event;
  - (c) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
  - (d) new findings in relation to any event referred to in points (a) to (c).

2. The sponsor shall report to all Member States where a clinical investigation is conducted without delay any of the following *by means of the electronic system referred to in Article 53*:
- (a) a serious adverse event that has a causal relationship with the investigational device, the comparator or the investigation procedure or where such causal relationship is reasonably possible;
  - (b) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
  - (c) new findings in relation to any event referred to in points (a) to (b).

The time period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial incomplete report followed up by a complete report.

3. The sponsor shall also report to the Member States concerned any event referred to in paragraph 2 occurring in third countries in which a clinical investigation is performed under the same clinical investigation plan as the one applying to a clinical investigation covered by this Regulation *by means of the electronic system referred to in Article 53*.

4. In the case of a clinical investigation for which the sponsor has used the single application referred to in Article 58, the sponsor shall report any event as referred to in paragraph 2 by means of the electronic system referred to in Article 53. Upon receipt, this report shall be transmitted electronically to all Member States concerned.

Under the direction of the coordinating Member State referred to in Article 58(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether a clinical investigation needs to be terminated, suspended, temporarily halted or modified.

This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.

5. In the case of post-market clinical follow-up investigations referred to in Article 54(1), the provisions on vigilance contained in Articles 61 to 66 shall apply instead of this Article.
6. ***Notwithstanding paragraph 5, this Article shall however apply where a causal relationship between the serious adverse event and the preceding investigational procedure has been established.***

## Article 60

### Implementing acts

The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of this Chapter as regards the following:

- (a) harmonised *electronic* forms for the application for clinical investigations and their assessment as referred to in Articles 51 and 58, taking into account specific categories or groups of devices;
- (b) the functioning of the electronic system referred to in Article 53;
- (c) harmonised *electronic* forms for the notification of post-market clinical follow-up investigations as referred to in Article 54(1), and of substantial modifications as referred to in Article 55;
- (d) the exchange of information between Member States as referred to in Article 56;
- (e) harmonised *electronic* forms for the reporting of serious adverse events and device deficiencies as referred to in Article 59;
- (f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 59.
- (g) ***uniform application of the requirements regarding the clinical evidence/data needed to demonstrate compliance with the general safety and performance requirements specified in Annex I.***

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

## *Article 60aa*

### *Requirements regarding other clinical investigations*

- 1. Clinical investigations, not ~~covered by~~ performed pursuant to any of the purposes listed in Article 50(1), shall comply with the provisions of Article 50 paragraphs 2, 3, 5 point (b), 5 point (c), 5 point (cb), 5 point (e), 5 point (h), 5 point (l) and 8 of this Regulation.*
- 2. In order to protect the rights, safety, dignity and well-being of subjects and the scientific and ethical integrity of the ~~non-commercial~~ clinical investigations not ~~covered by~~ performed pursuant to any of the purposes listed in Article 50(1), each Member State shall define any additional requirements for such investigations, as appropriate for each Member State concerned.*

## Chapter VII

### *Post-market surveillance, vigilance ~~Vigilance~~ and market surveillance*

#### **SECTION 0 – POST-MARKET SURVEILLANCE**

##### *Article 60a*

##### *Post-market surveillance system of the manufacturer*

- 1. ~~The manufacturer shall ensure compliance with the provisions of this Regulation throughout the entire lifetime of the devices he has made available on the market or put into service.~~*
- 2. For any device, proportionate to the risk class and appropriate for the type of device, manufacturers ~~of devices~~ shall plan, establish, document, implement, maintain and update a post-market surveillance system which shall be an integral part of the manufacturer's quality management system according to Article 8, ~~paragraph~~(6).*
- 3. The post-market surveillance system shall be suitable to actively and systematically gather, record and analyse relevant data on the quality, performance and safety of a device throughout its entire lifetime, to draw the necessary conclusions and to determine, implement and monitor any preventive and corrective actions.*
- 4. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:*
  - (a) to update the ~~risk/benefit risk determination analysis~~ and risk management, the design and manufacturing information, the instructions for use and the labelling;*
  - (b) to update the clinical evaluation;*
  - (c) to update the summary of safety and clinical performance as referred to in Article 26;*



- (d) *for the identification of needs for preventive, corrective or field safety corrective action;*
- (e) *for the identification of possibilities to improve the usability, performance and safety of the device;*
- (f) *when relevant, to contribute to the post-market surveillance of other devices.*
- (g) *to detect and report trends (in accordance with article 61a).*

*The technical documentation shall be updated accordingly.*

~~5. Updates according to paragraph 4 shall be reflected in the technical documentation.~~

6. *If in the course of the post-market surveillance a need for preventive and corrective action is identified, the manufacturer shall implement the appropriate measures and, where applicable, inform the notified body and the competent authorities concerned. ~~The identification of~~ When a serious ~~an~~ incident is identified or a field safety corrective action is implemented, this shall be reported in accordance with ~~shall induce actions according to~~ Article 61.*

#### *Article 60b*

##### *Post-market surveillance plan*

*The post-market surveillance system as referred to in Article 60a shall be based on a post-market surveillance plan, the requirements of which are set out in Section 1.1 of Annex IIa. For devices other than custom made-devices the post-market surveillance plan ~~which~~ shall be part of the technical documentation as specified in Annex II.*

## Article 60c

### Periodic safety update report

1. *Per device and where relevant per category or group of devices, the manufacturer shall prepare a periodic safety update report summarising the results and conclusions of the analyses of the gathered post-market surveillance data according to Annex IIa together with a rationale and description of any preventive and corrective actions taken.*

*Throughout the lifetime of the device concerned this report shall set out:*

- (a) *the conclusion of ~~conclude on~~ the benefit risk determination;*
- (b) *~~include~~ the main findings of the Post Market Clinical Follow-up Report and*
- (c) *the volume of sales of devices and an estimate of the population that use the device involved and, where ~~appropriate-practicable~~, for reusable medical devices the usage frequency of the device.*

*The report shall be updated at least annually; and, except for for custom made medical devices, be part of the technical documentation as specified in Annexes II and IIa.*

*For custom-made devices the report shall be part of the documentation referred to in Section 2 of Annex XI.*

2. *Manufacturers of devices in class III or implantable devices shall submit reports by means of the electronic system referred to in Article 66a to the notified body involved in the conformity assessment in accordance with Article 42. The notified body shall ~~will~~ review the report and add its evaluation to the database with details of any action taken. Such reports and the notified body evaluation shall be available to competent authorities through the electronic system.*
3. *Manufacturers of devices other than those referred to in paragraph 2, ~~I, IIa and IIb~~ shall make reports available to the notified body involved in the conformity assessment and to competent authorities on request.*

## SECTION 1 – VIGILANCE

### Article 61

#### *Reporting of serious incidents and field safety corrective actions*

1. Manufacturers of devices, ***made available on the Union market***, other than ~~custom-made or~~ investigational devices, shall report, through the electronic system referred to in Article ~~62~~ ***66a***, the following:
  - (a) any serious incident ~~in respect of~~ ***involving*** devices made available on the Union market, ***except expected serious 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 61a;***
  - (b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.
- 1a. As a general rule, the time period for reporting shall take account of the severity of the serious incident.***
- 1b. Manufacturers shall ~~make~~ provide the report any serious incident as referred to in point (a) the first subparagraph without delay, and no later than 15 days after they have become aware of the event and immediately after the manufacturer has established the causal relationship with their device or that such causal relationship is reasonably possible, and in not case later than 15 30 days after they have become aware of the event serious incident.***

~~The time period for reporting shall take account of the severity of the serious incident.~~

- 1c. Notwithstanding paragraph 1b, in case of a serious public health threat the report shall be provided immediately, and ~~in not case~~ later than 2 ~~ealendar~~ days after awareness by the manufacturer of this threat.*
- 1d. Notwithstanding paragraph 1b, in case of death or unanticipated serious deterioration in state of health the report shall be provided immediately after the manufacturer established or suspected a causal relationship ~~link~~ between the device and the ~~event~~ serious incident but not later than 10 elapsed ~~ealendar~~ days following the date of awareness of the ~~event~~ serious incident.*
- 1e. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.*
- 1f. If after becoming aware of a potentially reportable incident there is still uncertainty about whether the ~~event~~ incident is reportable, the manufacturer shall submit a report within the timeframe required for that type of incident.*
- 1g. Except in cases of urgency where the manufacturer need to undertake the field safety corrective action immediately, without undue delay, the manufacturer shall ~~provide the report~~ the field safety corrective action referred to in paragraph 1, point (b) ~~the second subparagraph~~ in advance of the field safety corrective action being undertaken.*

2. For similar serious incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented *or where the incidents are common expected and well documented, the* manufacturers may provide periodic summary reports instead of individual *serious* incident reports, on condition that the *coordinating competent authority referred to in Article 63(6), in consultation with the* competent authorities referred to in points (a), ~~and (b) and (c)~~ of Article *66a, paragraph 5-7 62(5), has* have agreed with the manufacturer on the format, content and frequency of the periodic summary reporting. *Where a single competent authority is referred to in points (a), (b) and (c) of Article 66a, paragraph 5 7, the manufacturer may provide periodic summary reports on agreement with that competent authority.*
  
3. The Member States shall take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities, ~~to the manufacturer and, where appropriate, to the authorised representative~~ suspected serious incidents referred to in point (a) of paragraph 1. They shall record such reports *that they receive* centrally at national level. Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the *suspected serious* incident.

The manufacturer *of the device concerned* shall *provide to the responsible competent authority of the Member State where the event serious incident occurred an initial a report on the serious incident in accordance with paragraph 1, or on the change in trend according to Article 61a, and* ensure the appropriate follow-up; *if the manufacturer considers that the event incident is does not fulfil the definition of a serious incident or an expected undesirable side effect which will be covered by trend reporting according to Article 61a, it shall provide or an explanatory statement why the incident is not a serious incident and ensure the appropriate follow-up.*

The Member States shall coordinate between them the development of standard web-based structured forms for reporting of serious incidents by healthcare professionals, users and patients.

- 3a.** *If the competent authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with this article ~~paragraph 1~~ and to take or require the manufacturer to take the that the manufacturer takes appropriate follow-up corrective action.*
- 3c.** *The Commission shall ensure that the electronic system referred to in Article 66a allows direct reporting from Member States' databases of any reports received pursuant to ~~paragraph 1.~~*
- 4.** ~~Manufacturers of custom-made devices shall report any serious incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the device in question has been made available.~~

#### *Article 64 61a*

##### *Trend reporting – ~~and periodic safety update reports by manufacturers~~*

- 1.** ~~Manufacturers of devices classified in class IIb and III shall report to~~ *by means of* the electronic system referred to in Article ~~62~~ **66a** any statistically significant increase in the frequency or severity of incidents that are not serious incidents or of expected undesirable side-effects that *could* have a significant impact on the risk-benefit analysis referred to in Sections **I.1** and **I.5** of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable side-effects in respect of the device, or category or group of devices, in question during a specific time period *as specified in the technical documentation and product information* ~~as established in accordance with the manufacturer's post market surveillance obligations pursuant to Article 60a(1)~~ conformity assessment. *The manufacturer shall define how to manage these ~~this~~ events serious incidents and the methodology used for determining any statistically significant increase in the frequency or severity of ~~this~~ these events incidents, as well as the observation period, in the post-market surveillance plan pursuant to article 60b.* ~~Article 63 shall apply.~~

- ~~1a. Trend reports on anticipated side-effects leading to serious incidents shall be automatically transmitted by the electronic system to the concerned member states. The provisions of article 63 shall apply.~~
- ~~1ab. The competent authorities may conduct their own assessments on the trend reports referred to in the first paragraph 1 and require the manufacturer to adopt appropriate measures in accordance with the present regulation in order to ensure the protection of public health and patient safety. The competent authority shall inform the Commission, the other competent authorities and the notified body that issued the certificate, of the results of such evaluation and of the adoption of such measures.~~
- ~~2. Manufacturers of implantable devices and devices falling within class III shall submit, by means of the electronic system referred to in Article 66a, periodic safety update reports including:~~
- ~~(a) summaries of data relevant to the benefits and risks of the medical devices, including results of all studies with a consideration of their potential impact on the certificate and the vigilance summary referred to in Article 61 (1);~~
  - ~~(b) a scientific evaluation of the risk-benefit ratio of the device;~~
  - ~~(c) all data relating to the volume of sales of the devices including an estimate of the population exposed to the device.~~
- ~~Manufacturers shall submit safety update reports annually during the period of validity of the first certificate. In case of certificate renewal, these reports shall be transmitted every two years.~~

*Article 62*

*Electronic system on vigilance*

1. ~~The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:~~
  - (a) ~~the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 61(1);~~
  - (b) ~~the periodic summary reports by manufacturers referred to in Article 61(2);~~
  - (c) ~~the reports by competent authorities on serious incidents referred to in the second subparagraph of Article 63(1);~~
  - (d) ~~the reports by manufacturers on trends referred to in Article 64;~~
  - (e) ~~the field safety notices by manufacturers referred to in Article 63(5);~~
  - (f) ~~the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 63(4) and (7).~~
  
2. ~~The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies.~~
  
3. ~~The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system.~~



4. ~~On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.~~
5. ~~The reports on serious incidents and field safety corrective actions referred to in points (a) and (b) of Article 61(1), the periodic summary reports referred to in Article 61(2), the reports on serious incidents referred to in the second subparagraph of Article 63(1) and the trend reports referred to in Article 64 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States:~~
- ~~(a) the Member State where the incident occurred;~~
  - ~~(b) the Member State where the field safety corrective action is being or is to be undertaken;~~
  - ~~(c) the Member State where the manufacturer has his registered place of business;~~
  - ~~(d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 45 for the device in question, is established.~~

#### *Article 63*

##### *Analysis of serious incidents and field safety corrective actions*

0. ***Following the reporting of a serious incident pursuant to Article 61, paragraph 1, the manufacturer shall without delay perform the necessary investigations of the serious incident and the concerned devices. This shall include a risk assessment of the incident and field safety corrective action taking into account criteria outlined in paragraph 2 as appropriate.***

***The manufacturer shall co-operate with the competent authorities and where relevant with the concerned notified body during these investigations 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.***

1. 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 61 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer, **and, where relevant, with the notified body concerned.**

~~If, in the case of reports received in accordance with Article 61(3), the competent authority ascertains that the reports relate to a serious incident, it shall notify without delay those reports to the electronic system referred to in Article 66a 62, unless the same incident has already been reported by the manufacturer.~~

2. ~~The~~ **In the context of the evaluation referred to in paragraph 10, the** national competent authorities ~~authority~~ shall, ~~in cooperation with the manufacturers and where relevant the notified bodies body concerned, evaluate assess the risks arising from~~ carry out a risk assessment with regard to ~~the~~ reported serious incidents ~~and~~ ~~or~~ field safety corrective actions, taking into account **the protection of public health and the** criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of **direct or indirect** harm and severity of **that** harm, clinical benefit of the device, intended and potential users, and population affected. ~~They~~ **It** shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action, **in particular taking into account the principle of inherent safety laid down in Annex I (xx).**

~~On~~ **Upon request by the national competent authority, the manufacturer shall provide for a [preliminary] risk assessment and/or provide all documents necessary for the risk assessment.**

- 2a. ~~They~~ *The national-competent authority authorities*, shall monitor the manufacturer's investigation of ~~the~~ *a serious* incident. *Where necessary, a competent authority may intervene in a manufacturer's investigation or initiate an independent investigation.*
- 2b. *The manufacturer shall provide a final report to the national-competent authority setting out its findings by means of the electronic system referred to in Article 66a. The report shall set out conclusions and where relevant indicate corrective actions to be taken.*
3. In the case of devices referred to in the first subparagraph of Article 1(4) and where the serious incident or field safety corrective action may 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 6 shall, *depending on whether a national* ~~inform the relevant~~ competent authority for medicinal products; or the European Medicines Agency (EMA), ~~that~~ was consulted by the notified body in accordance with ~~the second subparagraph of Article 42(2d)~~, *inform that competent authority or the EMA.*

In the case of devices covered by this Regulation in accordance with point (e) of Article 1(2) and where the serious incident or field safety corrective action may be related to the tissues or cells of human origin utilised for the manufacture of the device, the competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for human tissues and cells that was consulted by the notified body in accordance with ~~the third subparagraph of Article 42(2e)~~.

4. After carrying out the ~~assessment~~ *evaluation*, the evaluating competent authority shall, through the electronic system referred to in Article ~~66a~~ *62*, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or imposed on him to minimise the risk of recurrence of a serious incident, including information on the underlying events ~~serious incident~~ and the outcome of its assessment. *In all other cases, the evaluating competent authority shall provide to the manufacturer and, where applicable, to the reporting users and to the electronic system referred to in Article 66a, a final report on the outcome of its assessment.*

5. The manufacturer shall ensure that the users of the device in question are informed without delay of *information about the field safety corrective action taken is brought without delay to the attention of users of the device in question* by means of a field safety notice ~~in an official Union language which can be easily understood by the affected user or patient~~. *The field safety notice shall be edited in the an official Union language or languages determined by in one of the official languages of the Member State where the field safety corrective action is taken or in another language which the Member State has indicated that it can accept.* Except in case of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in cases referred to in paragraph 6 of this Article, the coordinating competent authority to allow them to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.

*The field safety notice shall, in particular,*

- (a) identify the affected device, indicating the following elements: type of device, model name and number, batch/lot or serial numbers and part or order number,*
- (b) describe the deficiencies or malfunctions as well as, where identified, their causes;*
- (c) describe the product's risks and the facts on which the risk assessment is based,*
- (d) clearly explain the potential hazard associated with the continued use of the device and the associated risk to the patient, user or other person*
- (e) clearly indicate the necessary corrective measures;*
- (f) indicate a contact person or a contact point for further questions;*
- (g) indicate any additional useful information.*

*The field safety notice shall allow the correct identification of the device or devices involved, including the UDI, and of the manufacturer, including the SRN, that has undertaken the field safety corrective action. The field safety notice shall explain, in a clear manner, without playing down the level of risk, the reasons for field safety corrective action with reference to the device deficiency or malfunction and associated risks for patient, user or other person and shall clearly indicate all the actions to be taken by users.*

~~*The manufacturer shall omit any comments or description that attempt to play down the level of risk in an inappropriate manner.*~~

The manufacturer shall enter the field safety notice in the electronic system referred to in Article ~~62~~ **66a** through which that notice shall be accessible to the public.

6. The competent authorities shall ~~designate~~ **nominate** a coordinating competent authority to coordinate their assessments referred to in paragraph 2 in the following cases:
- (a) where ***there is concern regarding a particular similar serious incident or cluster of serious*** incidents related to the same device or type of device of the same manufacturer ~~occur~~ in more than one Member State;
  - (b) where the ***appropriateness of a field safety corrective action that is proposed by a manufacturer is in question*** is being or is to be undertaken in more than one Member State ***is in question***.

Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be the one of the Member State where the manufacturer ***or the authorised representative*** has his registered place of business.

***The competent authorities shall actively participate in a coordination procedure developed by the MDCG. This procedure shall should include the following:***

- ***the designation of a coordinating authority on a case by case basis, when required;***
- ***a definition of the coordinated assessment process;***
- ***tasks and responsibilities of the coordinating authority and the involvement of other competent authorities in this process.***

The coordinating competent authority shall, ***through the electronic system referred to in Article 62 66a***, inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

7. ~~The coordinating competent authority shall carry out the following tasks:~~
- ~~(a) to monitor the investigation of the serious incident by the manufacturer and the corrective action to be taken;~~
  - ~~(b) to consult with the notified body that issued a certificate in accordance with Article 45 for the device in question regarding the impact of the serious incident on the certificate;~~
  - ~~(c) to agree with the manufacturer and the other competent authorities referred to in points (a) to (c) of Article 62 ~~66a~~(5) on the format, content and frequency of periodic summary reports in accordance with Article 61(2);~~
  - ~~(d) to agree with the manufacturer and other competent authorities concerned on the implementation of the appropriate field safety corrective action;~~
  - ~~(e) to inform the other competent authorities and the Commission, through the electronic system referred to in Article 62 ~~66a~~, of the progress in and the outcome of its assessment.~~

The designation of a coordinating competent authority shall not affect the rights of the other competent authorities to perform their own assessment and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating competent authority and the Commission shall be kept informed of the outcome of any such assessment and the adoption of any such measures.

8. The Commission shall provide ~~secretarial~~ **logistical administrative** support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.

#### *Article 64*

##### *Trend reporting*

~~Manufacturers of devices classified in class IIb and III shall report to the electronic system referred to in Article 62 any statistically significant increase in the frequency or severity of incidents that are not serious incidents or of expected undesirable side effects that have a significant impact on the risk-benefit analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable side effects in respect of the device, or category or group of devices, in question during a specific time period as established in the manufacturer's conformity assessment. Article 63 shall apply.~~

#### *Article 65*

##### *Documentation of vigilance data*

~~Manufacturers shall update their technical documentation with information on incidents received from healthcare professionals, patients and users, serious incidents, field safety corrective actions, periodic summary reports referred to in Article 61, trend reports referred to in Article 64 and field safety notices referred to in Article 63(5). They shall make this documentation available to their notified bodies, which shall assess the impact of the vigilance data on the conformity assessment and the certificate issued.~~

## Article 65a

### Analysis of vigilance data

*The Commission shall, in collaboration with the Member States, put in place systems and processes to proactively monitor the data available in the database referred to in Article 66a, in order to identify trends, patterns or signals in the data that may identify new risks or safety concerns.*

*When a previously unknown risks is identified or the ~~a~~ frequency's ~~increasing~~ of an anticipated risks ~~that~~ significantly and adversely changes the risk-benefit determination ~~ratio~~, the competent authority or, where appropriate, the coordinating competent authority shall inform the manufacturer, or where applicable the authorised representative, who shall take the necessary corrective actions ~~inform users in accordance with Article 63(5)~~.*

## Article 66

### Implementing acts

The Commission may, by means of implementing acts, *and after consultation of the MDCG*, adopt the modalities and procedural aspects necessary for the implementation of Articles ~~61 and 63~~ to 65a and 66a as regards the following:

- (a) typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;
- (b) ~~harmonised forms for~~ the reporting of serious incidents and field safety corrective actions, *field safety notices*, periodic summary reports, *periodic safety update reports* and trend reports by manufacturers as referred to in Articles 60c, 61, 61a and 63 ~~64~~;
- (ba) *standard web-based structured forms including a minimum data set for electronic reporting of serious incidents by healthcare professionals, users and patients*;
- (c) timelines for the reporting of ~~serious incidents and~~ field safety corrective actions, periodic summary reports, ~~and~~ trend reports *and periodic safety update reports* by manufacturers, taking into account the severity of the event *incident* to be reported as referred to in Articles 61 and 60c ~~64~~;
- (d) harmonised forms for the exchange of information between competent authorities as referred to in Article 63.



- (e) *procedures for designation of a coordinating competent authority; the coordinated assessment process; tasks and responsibilities of the coordinating competent authority and involvement of other competent authorities in this process.*

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

#### *Article 62 66a*

##### *Electronic system on vigilance and on post-market surveillance*

1. The Commission shall, in collaboration with the Member States, ~~set up and manage an electronic system to~~ collate and process the following information *by means of the electronic system set up pursuant to Article 27 including a link to the product information in accordance with article 24a 25:*
  - (a) the ~~initial and final~~ reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 61(1) *and Article 63 (12b)*;
  - (b) the periodic summary reports by manufacturers referred to in Article 61(2);
  - (c) ~~the reports by competent authorities on serious incidents referred to in the second subparagraph of Article 61(3)~~ 63(1);
  - (d) the reports by manufacturers on trends referred to in Article ~~64~~ *61a*;
  - (da) the periodic safety update reports referred to in Article 61a 60c;*
  - (e) the field safety notices by manufacturers referred to in Article 63(5);
  - (f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 63(4) and (7 6).
  
2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies *that issued a certificate for the device in question in accordance with Article 43.*

3. The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system.
4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.
5. The reports on serious incidents ~~and field safety corrective actions~~ referred to in points (a) ~~and (b)~~ of Article 61(1), the periodic summary reports referred to in Article 61(2), **and** the reports on serious incidents referred to in **Article 61(3)** the second subparagraph of Article 63(12) and the trend reports referred to in Article 64 **to (e) of paragraph 1** shall be automatically transmitted, upon receipt, via **through** the electronic system, to the competent ~~authorities~~ **authority** of the following Member States:
  - (a) ~~the Member State~~ where the incident occurred;
- 5a. ***Trend reports ~~on anticipated side-effects leading to serious incidents~~ referred to in points (a) of Article 61a(1) shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the Member State where the incidents occurred.***

6. *The reports on field safety corrective actions referred to in point (b) of Article 61(1) shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States:*
- (ba) the Member States where the field safety corrective action is being or is to be undertaken;
  - (eb) the Member State where the manufacturer *or his authorised representative* has his registered place of business;
  - (d) ~~where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 45 for the device in question, is established.~~
7. *The periodic summary reports referred to in Article 61(2) shall be automatically transmitted upon receipt via the electronic system to the competent authority of the following Member States:*
- (a) *the Member State(s) participating in the coordination procedure according to Article 63 (6) and that agreed on the periodic summary report;*
  - (b) *the Member State where the manufacturer or his authorised representative has his registered place of business.*
8. *The information referred to in paragraphs 5 to 7 shall be automatically transmitted, upon receipt, through the electronic system referred to in Article 62, to the notified body that issued the certificate for the device in question in accordance with Article 45.*

## SECTION 2 – MARKET SURVEILLANCE

### Article 67

#### *Market surveillance activities ~~at national level~~*

1. The competent authorities ~~for medical devices~~ shall perform appropriate checks on the *conformity* characteristics and performance of ~~the~~ devices ~~with the applicable legal requirements~~, including, where appropriate, ~~clinical evaluation~~, review of ~~technical~~ documentation and physical or laboratory checks on the basis of adequate samples. They shall, *in particular*, take account of ~~(a)~~ established principles regarding risk assessment and risk management, ~~(b)~~ vigilance data and ~~(c)~~ complaints.
  - 1a. *The competent authorities shall draw up annual surveillance activities plans and allocate a sufficient number of competent human and material resources needed to carry out those activities taking into account the European market surveillance program developed by the MDCG according to Article 80 and local circumstances.*

- 1b.** ~~The~~ *For the purpose referred to in the ~~previous~~ paragraph 1, the* competent authorities ~~may,~~  
*inter alia:*
- (a) *may, inter alia* require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and, where necessary and justified, ~~enter the premises of economic operators and take~~ *provide* the necessary samples of devices *free of charge*.
  - (b) *and shall ~~[may]~~ carry out both announced and, if necessary for control purposes, unannounced inspections of the premises of economic operators whose devices are intended to be made available on the Union market, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users. ~~To that purpose, they shall designate a sufficient number of competent inspectors.~~*
- 1c.** *The competent authorities shall prepare an annual summary of the results of the surveillance activities and make it accessible to other competent authorities by means of the electronic system referred to in Article 75b.*
- 1d.** *The competent authorities* ~~They~~ *may confiscate, destroy or otherwise render inoperable devices presenting an unacceptable serious risk or falsified products devices where they deem it necessary in the interest of the protection of public health.*
- 2.** The Member States shall ~~periodically~~ review and assess the functioning of their surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. The Member State concerned shall make a summary of the results accessible to the public *by means of the electronic system referred to in Article 75b.*

3. The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, ~~by means of the electronic system referred to in Article 75b to provide for a harmonized high level of market surveillance in all Member States.~~

Where appropriate, the competent authorities of the Member States shall agree on work-sharing, *joint market surveillance activities* and specialisation.

4. Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.
5. ~~The~~ *Where appropriate, the* competent authorities of the Member States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.

~~Without prejudice to any agreements between the EU and third countries, the inspections referred to in paragraph 1a may also take place in the premises established in a third country where the medical device is intended to be made available on the EU market.~~

6. ~~The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of this article as regards the good practices for market surveillance, particularly for inspection.~~  
~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).~~

## Article 68

### *Electronic system on market surveillance*

1. ~~The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information:~~
  - (a) ~~information in relation to non-compliant devices presenting a risk to health and safety referred to in Article 70(2), (4) and (6);~~
  - (b) ~~information in relation to compliant devices presenting a risk to health and safety referred to in Article 72(2);~~
  - (c) ~~information in relation to formal non-compliance of products referred to in Article 73(2);~~
  - (d) ~~information in relation to preventive health protection measures referred to in Article 74(2).~~
  
2. ~~The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States and to the Commission.~~

## Article 69

### *Evaluation regarding ~~suspected non-compliant~~ devices **suspected to presenting an unacceptable risk or non-compliance to health and safety at national level***

Where the ~~Member State~~ competent authorities of a Member State, based on **data obtained by vigilance or market surveillance activities** ~~data~~ or other information, have ~~sufficient~~ reason to believe that a device *may* presents **an unacceptable** risk to the health or safety of patients, users or other persons, **or to other aspects of the protection of public health, or otherwise does not comply with the requirements laid down in this Regulation**, they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by **or non-compliance of** the device. The relevant economic operators shall cooperate ~~as necessary~~ with the competent authorities.

## Article 70

### *Procedure for dealing with ~~non-compliant~~ devices presenting an **unacceptable** risk to health and safety*

1. Where, having performed an evaluation pursuant to Article 69, the competent authorities find that the device ~~according to that evaluation~~, which presents an **unacceptable** risk to the health or safety of patients, users or other persons, **or to other aspects of the protection of public health and** ~~does not comply with the requirements laid down in this Regulation~~, they shall without delay require the **manufacturer of the devices concerned, his authorised representatives and all other** relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to ~~prohibit or~~ restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period, proportionate to the nature of the risk **or non-compliance**. ~~The Competent Authority of the Member State in which the manufacturer of the concerned device is located shall be informed.~~
2. ~~The~~ Where the competent authorities consider that non-compliance is not restricted to their national territory, they shall ~~inform~~ **notify** the Commission, ~~and~~ the other Member States **and the notified body that issued a certificate in accordance with Article 45 for the device concerned** of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article ~~75b~~ **68**.
3. The economic operators shall ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.



4. Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate ~~provisional~~ measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it.

They shall notify the Commission, ~~and~~ the other Member States **and the notified body that issued a certificate in accordance with Article 45 for the device concerned**, without delay, of those measures, by means of the electronic system referred to in Article **75b** ~~68~~.

5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification **and tracing** of the non-compliant device ~~if available by means of the electronic system referred to in Article 25~~, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.

6. Member States other than the Member State initiating the procedure shall, without delay, inform the Commission and the other Member States, **by means of through the electronic system referred to in Article 75b**, ~~(a)~~ of any additional **relevant** information at their disposal relating to the non-compliance of the device concerned and ~~(b)~~ of any measures adopted by them in relation to the device concerned.

- ~~6a.~~ In the event of disagreement ~~of a Member State~~ with the ~~a~~ notified national measure ~~referred to in paragraph 4 or in point (b) of paragraph 6~~, they ~~the Member State~~ shall without delay inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article **75b** ~~68~~.

7. 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 **any** ~~provisional~~ measures taken by a Member State, ~~that~~ **those** measures shall be deemed **to be** justified.

8. ~~All~~ *Where paragraph 7 applies, all* Member States shall ensure that appropriate restrictive *or prohibitive* measures, *withdrawing, recalling or limiting the availability of the device on their national market* are taken without delay in respect of the device concerned.

#### Article 71

##### *Procedure for evaluating national measures at Union level*

1. Where, within two months of receipt of the notification referred to in Article 70(4) ~~and point (b) of 70(6)~~, objections are raised by a Member State against a ~~provisional~~ measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall, *after consulting the MDCG, and the national concerned competent authorities and, where necessary, the concerned economic operators*, evaluate the national measure. On the basis of the results of that evaluation, the Commission ~~shall~~ *may* decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).
2. If the national measure is considered justified, Article 70(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure. *In the absence of a Commission decision within six ~~one~~ month after the objection has been raised by a Member State or after the Commission has considered the measure to be contrary to the Union legislation, the national measures shall be considered to be justified.*

- 2a. Where, ~~in the situations referred to in Articles 70 and 72,~~ a Member State or the Commission consider that the risk to health and safety emanating from a device cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).
3. ~~On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts referred to in paragraphs 1 and 2a in accordance with the procedure referred to in Article 88(4).~~

#### *Article 72*

##### *Procedure for dealing with compliant devices presenting ~~an unacceptable~~ risk to health and safety*

1. ~~Where, having performed an evaluation pursuant to Article 69, a Member State finds that although a device has been legally placed on the market or put into service, it presents a **previously unknown unacceptable** risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health, it shall, *if it considers that the risk-benefit ratio has deteriorated to such an extent that the risk has become unacceptable,* require the relevant economic operator or operators to take all appropriate provisional measures **corrective actions** to ensure that the device concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the device from the market or to recall it within a reasonable period, proportionate to the nature of the risk.~~

2. ~~The Member State shall immediately notify the Commission and the other Member States of the measures taken, by means of the electronic system referred to in Article 68. That information shall include the data necessary for the identification of the device concerned, the origin and the supply chain of the device, the findings of the Member State's evaluation specifying the nature of the risk involved and the nature and duration of the national measures taken.~~
- 2a. ~~***The economic operators shall ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market.***~~
3. ~~The Commission shall evaluate the provisional national measures taken. On the basis of the results of that evaluation, the Commission shall *may* decide, by means of implementing acts, whether or not the measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(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 88(4).~~
4. ~~Where the national measure is considered justified, Article 70(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure. ***In the absence of a Commission decision the national measures shall be considered to be justified.***~~
5. ~~***The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.***~~

Article 73

Formal non-compliance

1. ~~Where, having performed an evaluation pursuant to Article 69, Without prejudice to Article 70, where the competent authorities of a Member State find that a device 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 put an end to the non-compliance concerned within a reasonable period that is proportionate to the non-compliance. where it makes **at least** one of the following findings, **related to formal non-compliance**:~~
- (a) ~~that the CE marking has been affixed in violation of the formal requirements laid down in Article 18;~~
  - (b) ~~that the CE marking has not been affixed to a device contrary to Article 18;~~
  - (c) ~~that the CE marking has been inappropriately affixed in accordance with procedures in this Regulation on a product that is not covered by this Regulation;~~
  - (d) ~~that the EU declaration of conformity has not been drawn up **in conformity with this Regulation and the requirements set out in Article 17 and Annex IV in particular** or is not complete;~~
  - (e) ~~that the information to be supplied by the manufacturer on the label or in the instructions for use is not available, not **in conformity with this Regulation and the requirements set out in Annex I Section III in particular** complete or not provided in the language(s) required;~~
  - (f) ~~that the technical documentation, including the clinical evaluation, is not available or not complete **in conformity with this Regulation and the requirements set out in Article 59 and Annex XIII in particular**;~~
  - (g) ~~that a conformity assessment according to Article 42 has not been carried out.~~

2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall 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 market. That Member State shall inform the Commission and the other Member States without delay of those measures, by means of the electronic system referred to in Article **75b** ~~68~~.
  
3. ***The Commission may, by means of implementing acts, elaborate details on the nature of non-compliances and appropriate measures to be taken by competent authorities to ensure the uniform application of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).***

#### Article 74

##### *Preventive health protection measures*

1. Where a Member State, after having performed an evaluation, which indicates a potential ~~previously unknown unacceptable~~ risk related to a device or a specific category or group of devices considers that, ***in order to protect the health and safety of patients, users or other persons or other aspects of public health***, the making available on the market or putting into service of ~~such a~~ ***a*** device or ***a*** specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled ~~in order to protect the health and safety of patients, users or other persons or other aspects of public health~~, it may take any necessary and justified ~~provisional~~ measures.
  
2. The Member State shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article **75b** ~~68~~.

3. The Commission, *in consultation with the MDCG and, where necessary, the concerned economic operators*, shall assess the ~~provisional~~ national measures taken. The Commission ~~shall~~ *may* decide, by means of implementing acts, whether the national measures are justified or not. *In the absence of a Commission decision within ~~three~~ six months from their notification, the national measures shall be considered to be justified.* Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(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 88(4).~~

4. Where the assessment referred to in paragraph 3 demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission ~~shall be empowered to~~ *may* adopt ~~delegated implementing~~ acts in accordance with *the examination procedure referred to in* Article 89 ~~88(3)~~ to take the necessary and duly justified measures.

~~Where in this case imperative grounds of urgency so require, the procedure provided for in Article 90 shall apply to delegated acts adopted pursuant to this paragraph.~~

## Article 75

### *Good administrative practice*

1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 70 to 74 shall state the exact grounds on which it is based. Where it is addressed to a specific economic operator, it shall be notified without delay to the economic operator concerned, who shall at the same time be informed of the remedies available to him under the law **or the administrative practice** of the Member State concerned and of the time limits to which such remedies are subject. Where the measure is of general scope, it shall be appropriately published.
2. Except in cases where immediate action is necessary for reasons of **unacceptable** ~~serious~~ risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time before any measure is adopted. If action has been taken without the economic operator's being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.
3. Any **provisional** measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that he has taken effective corrective action **and that the device is in compliance with the requirements of this Regulation**.
4. Where a measure adopted pursuant to Articles 70 to 74 concerns a product for which a notified body has been involved in the conformity assessment, the competent authorities shall **by means of the electronic system referred to in Article 75b** inform the relevant notified body **and the authority responsible for the notified body** of the measure taken.



Article 75b 68

*Electronic system on market surveillance* ~~Market surveillance module in EUDAMED~~

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information: ~~by means of the electronic system referred to in point (g) of Article 27(2)~~
  - (aa) *summaries of the results of the surveillance activities referred to in Article 67 69(1c);*
  - (a) information in relation to ~~non-compliant~~ devices presenting an *unacceptable* risk to health and safety referred to in Article 70(2), (4) and (6);
  - (b) ~~information in relation to compliant devices presenting a risk to health and safety referred to in Article 72(2);~~
  - (c) information in relation to formal non-compliance of products referred to in Article 73(2);
  - (d) information in relation to preventive health protection measures referred to in Article 74(2);
  - (e) *summaries of the results of the reviews and assessments of the surveillance activities of the Member States referred to in 67(2).*
2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned *and, where applicable, to the notified body that issued a certificate in accordance with Article 45 for the device concerned* and be accessible to the Member States and to the Commission.
3. *Information exchanged between Member States shall not be made public when this may impair market surveillance activities and co-operation between Member States.*

# Chapter VIII

## Cooperation between Member States, Medical Device Coordination Group, ~~EU-reference~~ *Expert laboratories, Expert panels and device registers*

### *Article 76*

#### *Competent authorities*

1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate ***the names and contact details of*** the competent authorities ~~***responsible for the implementation of this Regulation***~~ to the Commission which shall publish a list of competent authorities.
  
2. ~~For the implementation of Articles 50 to 60, the Member States may designate a national contact point other than a national authority. In this case, references to a competent authority in this Regulation shall be understood as including the national contact point.~~

### *Article 77*

#### *Cooperation*

1. The competent authorities of the Member States shall cooperate with each other and with the Commission ~~and~~ ***which shall provide for the organisation of*** exchanges ~~with each other of~~ ~~the~~ information necessary to enable this Regulation to be applied uniformly.
  
2. Member States ***shall with the support of*** ~~and~~ the Commission shall participate, ***where appropriate,*** in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.

## Article 78

### Medical Device Coordination Group

1. A Medical Device Coordination Group (MDCG) is hereby established.
2. Each Member State shall appoint, for a three-year term which may be renewed, one member and one alternate providing expertise in the field of this Regulation, and one member and one alternate providing expertise in the field of Regulation (EU) No [.../...] [on *in vitro* diagnostic medical devices] A Member State may choose to appoint only one member and one alternate providing expertise in both fields.

The members of the MDCG shall be chosen for their competence and experience in the field of medical devices and *in vitro* diagnostic medical devices. They shall represent the competent authorities of the Member States. The names and affiliation of members shall be made public by the Commission.

The alternates shall represent and vote for the members in their absence.

3. The MDCG shall meet at regular intervals and, where the situation requires, **upon** a request from the Commission or a Member State. The meetings shall be attended either by the members appointed for their role and expertise in the field of this Regulation, or by the members appointed for their expertise in the field of Regulation (EU) No [.../...] [on *in vitro* diagnostic medical devices], or by the members appointed for both Regulations, **or their alternates**, as appropriate.
4. The MDCG shall use its best endeavours to reach consensus. If such consensus cannot be reached, the MDCG shall decide by the majority of its members. Members with diverging positions may request that their positions and the grounds on which they are based are recorded in the MDCG's position.
5. The MDCG shall be chaired by a representative of the Commission. The chair shall not take part in votes of the MDCG.

6. The MDCG may invite, on a case-by-case basis, experts and other third parties to attend meetings or provide written contributions.
7. The MDCG may establish standing or temporary sub-groups. Where appropriate, organisations representing the interests of the medical device industry, healthcare professionals, laboratories, patients and consumers at Union level shall be invited in such sub-groups in the capacity of observers.
8. The MDCG shall establish its rules of procedure which shall, in particular, lay down procedures for the following:
  - the adoption of opinions or recommendations or other positions by the MDCG, including in cases of urgency;
  - the delegation of tasks to reporting and co-reporting members;
  - ***the implementation of Article 82 regarding conflict of interests;***
  - the functioning of sub-groups;
  - ***procedures for appointing and replacing the Chairman.***

~~The rules of procedure shall enter into force after receiving a favourable opinion from the Commission.~~

#### *Article 79*

##### *Support by the Commission*

The Commission shall support the functioning of the cooperation between national competent authorities. ***It shall, in particular, provide for the organisation of exchanges of experience between the competent authorities*** and provide technical, scientific and logistic support to the MDCG and its sub-groups. It shall organise the meetings of the MDCG and its sub-groups, participate in those meetings and ensure the appropriate follow-up.

Article 80

Tasks of the MDCG

The MDCG shall have the following tasks:

- (a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;
- ~~(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 44;~~
- (c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical evaluation *and investigations* by manufacturers, ~~and~~ the assessment by notified bodies *and the vigilance activities*;
- (ca) to contribute to ~~the~~ the continuous monitoring of the technical progress and assessment whether the general safety and performance requirements provided in this Regulation and Regulation (EU) No [.../...] [on in vitro diagnostic medical devices] are appropriate to ensure safety and performance of medical devices and identify the need to amend Annex I;*
- (cb) to contribute to the development of devices standards, of Common Specifications and of scientific guidelines on clinical investigation of certain devices in particular implantable and class III devices;*
- (d) to assist the competent authorities of the Member States in their coordination activities *in particular* in the fields of *classification and regulatory status of devices*, clinical investigations, vigilance and market surveillance *including the development and maintenance of a framework for a European market surveillance program with the objective of efficiency and harmonisation of market surveillance in the European Union, in accordance with Article 67*;
- (e) to provide advice ~~and assist the Commission~~, *either on its own initiative or* at its request *of the Commission*, in ~~its~~ *the* assessment of any issue related to the implementation of this Regulation;
- (f) to contribute to harmonised administrative practice with regard to ~~medical~~ devices in the Member States.

*Article 81*

*European Union reference laboratories*

1. ~~For specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices, the Commission may designate, by means of implementing acts, one or more European Union reference laboratories, hereinafter referred to as 'EU reference laboratories', that satisfy the criteria set out in paragraph 3. The Commission shall only designate laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation.~~
  
2. ~~Within the scope of their designation, the EU reference laboratories shall, where appropriate, have the following tasks:~~
  - (a) ~~to provide scientific and technical assistance to the Commission, the Member States and notified bodies in relation to the implementation of this Regulation;~~
  - (b) ~~to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices;~~
  - (c) ~~to set up and manage a network of national reference laboratories and publish a list of the participating national reference laboratories and their respective tasks;~~
  - (d) ~~to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures and market surveillance;~~
  - (e) ~~to collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;~~
  - (f) ~~to contribute to the development of standards at international level;~~
  - (g) ~~to provide scientific opinions in response to consultations by notified bodies in accordance with this Regulation.~~

3. ~~EU reference laboratories shall satisfy the following criteria:~~
- ~~(a) to have appropriately qualified staff with adequate knowledge and experience in the field of the medical devices for which they are designated;~~
  - ~~(b) to possess the necessary equipment and reference material to carry out the tasks assigned to them;~~
  - ~~(c) to have the necessary knowledge of international standards and best practices;~~
  - ~~(d) to have an appropriate administrative organisation and structure;~~
  - ~~(e) to ensure that their staff observe the confidentiality of the information and data obtained in carrying out their tasks.~~

4. ~~EU reference laboratories may be granted a Union financial contribution.~~

~~The Commission may adopt, by means of implementing acts, the modalities and the amount of the grant of a Union financial contribution to EU reference laboratories, taking into account the objectives of protection of health and safety, support of innovation and cost effectiveness. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).~~

5. ~~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 the requested task according to a set of predetermined and transparent terms and conditions.~~
6. ~~The Commission shall be empowered to adopt delegated acts in accordance with Article 89 for the following purposes:~~
- ~~(a) amending, or supplementing the tasks of EU reference laboratories referred to in paragraph 2 and the criteria to be satisfied by EU reference laboratories referred to in paragraph 3.~~

- (b) ~~setting out the structure and the level of the fees referred to in paragraph 5 which may be levied by an EU Reference Laboratory for providing scientific opinions in response to consultations by notified bodies in accordance with this Regulation, taking into account the objectives of protection of human health and safety, support of innovation and cost effectiveness.~~
7. ~~EU reference laboratories shall be subject to controls, including on-site visits and audits, by the Commission to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements for which they have been designated, the Commission, by means of implementing acts, shall take appropriate measures, including the withdrawal of the designation.~~

#### *Article 81a*

##### *Provision of scientific, technical and clinical opinion and advice*

1. *~~The Commission shall, in consultation with the MDCG and in cooperation with the Joint Research Centre, make provision for expert panels and expert laboratories to be appointed for the assessment of the clinical evaluation in relevant medical fields as referred to in Paragraph 5abis and, where necessary, for categories or groups of devices, or for specific hazards relating to categories or groups of devices, under the principles of highest scientific competence, impartiality, independence and transparency. The same principles shall apply where the Commission decides to appoint expert laboratories in accordance with paragraph 5.~~*
  
2. *Expert panels and expert laboratories may be appointed in areas where the Commission, in consultation with the MDCG, has identified a need for the provision of consistent scientific, technical and/or clinical advice or laboratory expertise in relation to the implementation of this Regulation. Expert panels and expert laboratories may be appointed on a standing or temporary basis.*



3. *Expert panels shall consist of advisors appointed by the Commission on the basis of up-to-date clinical, scientific or technical expertise in the field and with a geographical distribution that reflects the diversity of scientific and clinical approaches in the Union. The Commission shall determine the number of members of each panel in accordance with the requisite needs.*

*The members of expert panels shall perform their tasks with impartiality and objectivity. They shall be completely independent and shall neither seek nor take instructions from notified bodies or manufacturers. Each member shall draw up a declaration of interests which shall be made publicly available.*

*The Commission shall establish systems and procedures to actively manage and prevent potential conflicts of interest.*

4. *The Commission, following consultation with the MDCG, may appoint advisors to expert panels following publication in the Official Journal of the European Union and on the Commission website ~~or~~ following a call for expressions of interest. Depending on the type of task and the need for specific expertise, advisors may be appointed to the expert panels for a maximum period of three years and their appointment may be renewed.*

- 4a. *The Commission, following consultation with the MDCG, may include advisors on a central 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 panel as needed. This list shall be published on the Commission website.*

5. *Expert laboratories may be appointed by the Commission, following consultation with the MDCG ~~[and in cooperation with the Joint Research Centre]~~, on the basis of their expertise in physico-chemical characterisation, microbiology/~~biological/biocompatibility~~, biocompatibility, mechanical, electrical, electronic or non-clinical biological/toxicological testing of specific devices, categories or groups of devices. The Commission shall only appoint expert laboratories for which a Member State or the Joint Research Centre have submitted an application for designation.*

- 5a. *Expert panels appointed for the clinical evaluation in relevant medical fields shall fulfil the task specified in Article 42(2a) and 49 and Section 6.0 of Chapter II of Annex VIII or Section 6 of Annex IX, as applicable.*
6. *Expert panels and expert laboratories may have the following tasks, depending on the requisite needs:*
- (a) *to provide scientific, technical and clinical assistance to the Commission and MDCG in relation to the implementation of this Regulation;*
  - (b) *to contribute to the development and maintenance of appropriate guidance and common specifications for clinical investigations, clinical evaluation and PMCF and for physico-chemical characterisation, microbiological/biocompatibility, biocompatibility mechanical, electrical, electronic or non-clinical toxicological testing for specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices;*
  - (c) *to develop and review ~~best practices~~ clinical evaluation guidance for the state of art performance of conformity assessment procedures with regard to clinical evaluation, physico-chemical characterisation, ~~microbiological/biocompatibility~~, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing;*
  - (d) *to contribute to the development of standards at international level, ensuring that these reflect the state of the art;*
  - (e) *to provide opinions in response to consultations by manufacturers in accordance with Article 49(21a), notified bodies and Member States in accordance with paragraphs 7-9.*
  - (f) *~~to provide early advice on the clinical evaluation to manufacturer regarding devices for implantable [and invasive devices] classified as class III which are listed in annex XX;~~ to contribute to identification of concerns and emerging issues on the safety and performance of medical devices;*

7. *The Commission, ~~[in cooperation with the Joint Research Centre]~~, shall facilitate the access of Member States and notified bodies and manufacturers to advice provided by expert panels and expert laboratories concerning, among others, the criteria for an appropriate data set for assessment of the conformity of a device, in particular with regard to the clinical data required for the clinical evaluation and with regard to physico-chemical characterisation, microbiological/~~biocompatibility~~, biocompatibility, mechanical, electrical, ~~electronical~~ or non-clinical toxicological testing.*
8. *When adopting its scientific opinion in accordance with paragraph 5a~~is~~, 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 the majority of their members, and the scientific opinion shall mention the divergent positions and the grounds on which they are based.*

*The Commission shall publish the scientific opinion and advice delivered in accordance with paragraphs 5a~~is~~ and 7, ensuring consideration of aspects of confidentiality as set out in Article 84. The clinical evaluation guidance referred to in paragraph 6(c) shall be published following consultation with MDCG.*

9. *Manufacturers and notified bodies may be subject to pay fees to the Joint Research Centre for the advice provided by expert panels and expert laboratories except if the procedure is initiated in accordance with Annex VIII Section 6.0(c) of Chapter II and the fees are exempted by the Commission. The structure and the level of fees shall be adopted by the Commission by means of implementing acts in accordance with the examination procedure referred to in Article 88(3), 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.*
10. *The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend or supplement the tasks of expert panels and expert laboratories referred to in paragraph 5~~6~~.*

## Article 82

### *Conflict of interests*

1. Members of the MDCG, *its sub-groups*, and *members of experts panels and expert laboratories* ~~staff of the EU reference laboratories~~ shall not have financial or other interests in the medical device industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct and indirect interests they may have in the medical device industry and update this declaration whenever a relevant change occurs. Upon request, the declaration of interests shall be accessible to the public. This Article shall not apply to the representatives of stakeholder organisations participating in the sub-groups of the MDCG.
2. Experts and other third parties invited by the MDCG on a case-by-case basis shall ~~be requested to declare their~~ *any* interests *they may have* in the issue in question.

## Article 83

### *Device registers*

The Commission and the Member States shall take all appropriate measures to encourage the establishment of registers for specific types of devices ~~to gather post-market experience related to the use of such devices~~ *setting common principles to collect comparable information*. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices *and/or to the traceability of implantable devices*.

# Chapter IX

## Confidentiality, data protection, funding, penalties

### Article 84

#### Confidentiality

1. Unless otherwise provided in this Regulation and without prejudice to existing national provisions and practices in the Member States on ~~medical~~ confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:
  - (a) personal data in compliance with **Article 85** ~~Directive 95/46/EC and Regulation (EC) No 45/2001~~;
  - (b) commercially **confidential information** ~~interests~~ **and trade secrets** of a natural or legal person, including intellectual property rights; **unless disclosure is in the public interests**;
  - (c) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.
2. Without prejudice to paragraph 1, information exchanged between competent authorities and between competent authorities and the Commission on condition of confidentiality shall ~~remain confidential unless~~ **shall not be disclosed without prior agreement with** the originating authority ~~has agreed to its disclosure~~.
3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.
4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

*Article 85*

*Data protection*

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.
2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

*Article 86*

*Levy of fees*

1. This Regulation shall be without prejudice to the possibility for Member States 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. ~~They~~
2. **Member States** shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted.

## *Article 86a*

### *Funding of notified body designation and monitoring activities*

- 1a. The cost associated with the joint assessment activities shall be covered by the Commission. The Commission shall lay down the scale and structure of recoverable costs and other necessary implementing rules. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).*

## *Article 87*

### *Penalties*

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. The Member States shall notify those provisions to the Commission by [*3 months prior to the date of application of the Regulation*] and shall notify it without delay of any subsequent amendment affecting them.

# Chapter X

## Final provisions

### Article 88

#### Committee procedure

1. The Commission shall be assisted by a Committee on Medical Devices. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

***Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.***

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or Article 5, as appropriate, shall apply.

### Article 89

#### Exercise of the delegation

1. The power to adopt the delegated acts referred to in Articles 2(2) and (3), 4(5), 8(2), 17(4), 24(7a), 25(7), 29(2), 40(2), 41(4), 42(11), 45(5), 51(7), 53(3), 74(4) and 81(6), **81a(10)** is conferred on the Commission subject to the conditions laid down in this Article. ***When adopting those delegated acts, the Commission shall follow its usual practice and carry out consultations with experts, including Member States' experts.***



2. The ~~delegation of power~~ **to adopt delegated acts** referred to in Articles **1(1c)**, ~~2(2) and (3)~~, ~~4(5)~~, 8(2), 17(4), **24(7a)**, ~~25(7)~~, ~~29(2)~~, ~~40(2)~~, ~~41(4)~~, 42(11), 45(5), ~~51(7)~~, ~~53(3)~~, ~~74(4)~~, and ~~81(6)~~; **81a(10)** shall be conferred on the Commission for ~~an indeterminate period of time~~ **a period of five years** from the date of entry into force of this Regulation. **The Commission shall draw up a report in respect of the ~~delegated~~ delegation of powers not later than six months before the end of the five year period. The delegation of powers shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**
3. The delegation of power referred to in Articles **1(1c)**, ~~2(2) and (3)~~, ~~4(5)~~, 8(2), 17(4), **24(7a)**, ~~25(7)~~, ~~29(2)~~, ~~40(2)~~, ~~41(4)~~, 42(11), 45(5), ~~51(7)~~, ~~53(3)~~, ~~74(4)~~ and ~~81(6)~~; **81a(10)** may be revoked at any time by the European Parliament or by the Council. A decision ~~of revocation~~ **to revoke** shall put an end to the delegation of the power specified in that decision. It shall take effect the day following ~~its~~ publication **of the decision** in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to ~~any of the~~ Articles **1(1c)** ~~2(3)~~, **8(2)**, **17(4)**, **24(7a)**, **42(11)**, **45(5)** and **81a(10)** ~~listed in paragraph 1~~ shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of ~~two~~ **three** months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period ~~may~~ **shall** be extended by ~~two~~ **three** months at the initiative of the European Parliament or **of** the Council.

*Article 90*

*Urgency procedure for delegated acts*

1. ~~Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.~~
2. ~~Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 89. In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or the Council.~~

*Article 90a*

*Separate delegated acts for different delegated powers*

*The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation.*

## Article 91

### Amendments to Directive 2001/83/EC

In Annex I of Directive 2001/83/EC, point 12 of Section 3.2. is replaced by the following:

‘(12) Where a product is governed by this Directive in accordance with the second subparagraph of Article 1(4) or the second subparagraph of Article 1(5) of Regulation (EU) [.../...] on medical devices<sup>35</sup>, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements of Annex I of that Regulation 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.

If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) [.../...], the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements of Annex I of that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question, ~~unless the authority is advised by its experts for medical devices that involvement of a notified body is not required.~~’

## Article 92

### Amendments to Regulation (EC) No 178/2002

In the third subparagraph of Article 2 of Regulation (EC) No 178/2002, the following point (i) is added:

‘(i) medical devices within the meaning of Regulation (EU) [.../...]<sup>36</sup>,

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<sup>35</sup> OJ L [...], [...], p. [...].

<sup>36</sup> OJ L [...], [...], p. [...].

### Article 93

#### Amendments to Regulation (EC) No 1223/2009

In Article 2 of Regulation (EC) No 1223/2009, the following paragraph is added:

4. In accordance with the regulatory procedure referred to in Article 32(2), the Commission may, at the request of a Member State or on its own initiative, adopt the necessary measures to determine whether or not a specific product or group of products falls within the definition ‘cosmetic product’.

### Article 94

#### Transitional provisions

1. From the date of application of this Regulation any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC shall become void.
2. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 of Directive 90/385/EEC or Annex IV of Directive 93/42/EEC which shall become void at the latest two years after the date of application of this Regulation.

Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC after the entry into force of this Regulation shall **remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its delivery. They shall however** become void at the latest ~~two~~ **five** years after the date of application of this Regulation.

3. By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market before its date of application.

- 3a. *Devices which were lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to the date referred to in Article 97(2) may continue to be made available until 5 years after that date.*
4. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.
5. By way of derogation from Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, manufacturers, authorised representatives, importers and notified bodies who, during the period from [date of application] until [18 months after date of application], comply with Article 25(23) and **Article 25a(1)** (~~3~~) and Article 45(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with, respectively, Article 10a of Directive 90/385/EEC or Article 14(1) and (2) of Directive 93/42/EEC and with, respectively, point (a) of Article 10b(1) of Directive 90/385/EEC or points (a) and (b) of Article 14a(1) of Directive 93/42/EEC as specified in Commission Decision 2010/227/EU.
6. Authorisations granted by competent authorities of the Member States in accordance with Article 9(9) of Directive 90/385/EEC or Article 11(13) of Directive 93/42/EEC shall keep the validity indicated in the authorisation.
7. Devices falling within the scope of this Regulation in accordance with point (e) **and (ea)** of Article 1(2) which have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to the application of this Regulation may continue to be placed on the market and put into service in the Member States concerned.

8. Clinical investigations which have started to be conducted in accordance with Article 10 of Directive 90/385/EEC or Article 15 of Directive 93/42/EEC prior to the application of this Regulation may continue to be conducted. As of the application of this Regulation, however, the reporting of serious adverse events- ~~incidents~~ and device deficiencies shall be carried out in accordance with this Regulation.
9. ***Until the Commission in line with Article 24(2) has designated the UDI assigning entities, GS1 AISBL, HIBCC and ICCBBA shall be considered as designated UDI assigning entities.***

*Article 95*

*Evaluation*

No later than seven years after the date of application, the Commission shall assess the application of this Regulation and establish an evaluation report on the progress towards achievement of the objectives of the Regulation including an assessment of resources required to implement this Regulation.

*Article 96*

*Repeal*

Council Directives 90/385/EEC and 93/42/EEC are repealed with effect from ***[the later of the two dates referred to in Article 97(2) and 97(3)(d)]*** ~~*[date of application of this Regulation]*~~, with the exception of ***Article 10***, Article 10a and point (a) of Article 10b(1) ***and Annex 7*** of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) ***and Article 15 and Annex X*** of Directive 93/42/EEC which are repealed with effect from ***18 months after the later of the two dates referred to in Article 97(2) and 97(3)(d)*** ~~*[18 months after date of application]*~~.

References to the repealed Council Directives shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid down in Annex XVI.

## Article 97

### *Entry into force and date of application*

1. This Regulation shall enter into force on the twentieth day after its publication in the *Official Journal of the European Union*.
2. It shall apply from [*three years after entry into force*].
3. By way of derogation from paragraph 2 the following shall apply:
  - (a) ~~Article 25(2) and (3) and Article 45(4) shall apply from [18 months after date of application referred to in paragraph 2];~~
  - (b) Articles 28 to 40 and Article 78 shall apply from [*six months after entry into force*].  
However, prior to [*date of application as referred to in paragraph 2*], the obligations on notified bodies emanating from the provisions in Articles 28 to 40 shall apply only to those bodies which submit an application for notification in accordance with Article 31 of this Regulation.
    - (ba) *Article 25a(5), Article 26, Article 27(3), Chapter VI except Articles 49, 50, 50c, 50d and 60aa, Article 60c(2), Article 65a and Article 66a shall apply from six months after the publication of the notice referred to in Article 27a(3), but in any event no earlier than the point in time referred to in paragraph 2.*
    - (bb) *Article 24(3), Article 24b, Article 25(3) paragraphs 1 to 4 of Article 25a and Article 45(4) shall apply from 18 months after the date of application referred to in point (ba).*
    - (c) *For implantable devices and Class III devices Article 24(4) shall apply one year after the date of application of this regulation. For Class IIa and Class IIb devices Article 24(4) shall apply three years after the date of application of this regulation. For Class I devices Article 24(4) shall apply five years after the date of application of this regulation.*
    - (ca) *For reusable devices that shall bear the UDI Carrier on the device itself, Article 24(4) shall apply two years after the date applicable for its class of devices as stipulated in point (c).*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, ~~26.9.2012~~

*For the European Parliament*

*For the Council*

*The President*

*The President*

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