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2025/0133 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications

(Text with EEA relevance)

{SWD(2025) 130 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

In its Communication on 'Long-term competitiveness of the EU: looking beyond 2030'[1], the Commission stressed the importance of a regulatory system that ensures objectives are reached at minimum costs. To that end, it committed to a dedicated effort to rationalise and simplify reporting requirements and administrative burdens, with the ultimate aim of reducing such requirements by 25% without undermining the related policy objectives.

Reporting requirements play a key role in ensuring the correct enforcement and proper monitoring of legislation. The costs of reporting are overall largely offset by the benefits they bring, in particular as regards monitoring and ensuring compliance with key policy measures. However, reporting requirements can also impose a disproportionate burden on stakeholders, particularly SMEs and micro-companies. The accumulation of these requirements over time can result in redundant, duplicate or obsolete obligations, inefficient frequency and timing, or inadequate methods of collection. The Commission promotes the 'digital by default' principle in its Digital Strategy/Better regulation to support digital transformations, facilitating digital-ready policies that take into account the fast-evolving world of digitalisation and technology, and are digital, interoperable, future-proof and agile by default.[2]

The Communication 'A Competitiveness Compass for the EU'[3] highlights that digitalisation goes hand in hand with simplification to reduce reporting burdens. The Communication emphasises that reporting should move to digital formats based on standardised data. However, where digital procedures exist today, aspects such as fragmented IT ecosystems, and inefficient data exchanges all make it burdensome for businesses to interact with public authorities digitally.

The upcoming European Business Wallets initiative will address these challenges by establishing digital identity for all economic operators and by providing the framework for interoperable Business Wallets sharing verified data and credentials, enabling seamless digital interactions between economic operators and public administrations across the Union. This way, the European Business Wallets will build on the already existing digital solutions designed to simplify everyday activities for European economic operators, such as the Single Digital Gateway, the Once Only Technical System ('OOTS'), the Digital Product Passport ('DPP'), eInvoice, thus building a cohesive ecosystem of digital solutions that will maximise synergies and foster greater economic integration and innovation throughout Europe

However, there are still various pieces of EU legislation that provide for the use of paper format.

Removing references to paper format would also force public authorities to rethink the ways they process submissions or reporting by companies. Streamlining such submissions and reporting by promoting digital-by-default would create new incentives to invest in data collection and processing with eGovernment solutions that could pave the way to a document-free Single Market based on interoperable structured data and the once-only principle.

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1 COM(2023)168.

2 https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en

3 COM/2025/30 final.

While the New Legislative Framework ('NLF') does not impose a particular format for the instructions for use accompanying the products, practice has shown that most market surveillances authorities expect those instructions to be in paper format and therefore impose this format on manufacturers.

The Blue Guide[4] provides detailed explanations on EU product rules.

Taking into account that in 2024, no less than 94% of EU households had access to internet[5], the paper format of instructions for use accompanying products under the scope of the Directives is outdated and not aligned with current technologies, consumer habits or green objectives.

Consequently, manufacturers should be able to choose a digital format for instructions for use. Where manufacturers choose to provide instructions for use in digital format, the safety information (including any parts of the instructions for use deemed imperative for safety) should still be provided in paper format to protect the safety of consumers. Moreover, end-users should be able to obtain a paper copy of the instructions upon request – at the time of purchase and for a certain period of time after purchase.

Streamlining reporting obligations, reducing administrative burdens and promoting digitalisation are priorities. In this context, the present proposal aims to simplify initiatives included in the headline ambition 'A new plan for Europe's sustainable prosperity and competitiveness' in the policy area of the Internal Market, Food safety and Health impacting a multitude of sectors.

Moreover, the Communication 'A Competitiveness Compass for the EU' identified the need to seek for alternative options to give businesses legal certainty regarding compliance with EU rules in situations where harmonised standards do not exist, are not available, are not sufficient, or there is an urgent need. Several existing legislative acts already contain an alternative option to provide businesses with legal predictability and prove compliance with EU law, to cater for such situations. The present proposal's objective is to align the alternative option in legislative acts which do not provide for any alternative option to harmonised standards. The alternative option is to be implemented in a uniform manner as regards definition, legal effect, the conditions under which that alternative option may be adopted and adoption procedure. The initiative on common specifications is fully in line with the need referred to above and aims to simplify the life of businesses that have to comply with one or more product-specific health and safety requirements, as enshrined in sectoral regulations that make use of harmonised standards.

The proposal aims to rationalise and digitalise economic operators' obligations for Directive 2000/14/EC on the noise emission in the environment by equipment for use outdoors,[6] Directive 2010/35/EU on transportable pressure equipment,[7] Directive 2011/65/EU on

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4 Commission notice The 'Blue Guide' on the implementation of EU product rules 2022 (Text with EEA relevance) 2022/C 247/01, C/2022/3637 (OJ C 247, 29.6.2022, p. 1)

5 Source: Digital economy and society statistics - households and individuals - Statistics Explained

6 Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 3.7.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/14/oj).

7 Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1, ELI: http://data.europa.eu/eli/dir/2010/35/oj).

restriction of hazardous substances in electrical and electronic equipment,[8] Directive 2013/53/EU on recreational craft and personal watercraft,[9] Directive 2014/29/EU on simple pressure vessels,[10] Directive 2014/30/EU on electromagnetic compatibility,[11] Directive 2014/31/EU on non-automatic weighing instruments,[12] Directive 2014/32/EU on measuring instruments,[13] Directive 2014/33/EU on lifts and safety components for lifts,[14] Directive 2014/34/EU on equipment and protective systems intended for use in potentially explosive atmospheres,[15] Directive 2014/35/EU on electrical equipment designed for use within certain voltage limits,[16] Directive 2014/53/EU on radio equipment,[17] Directive 2014/68/EU on pressure equipment[18] and Directive 2014/90/EU on marine equipment[19] by a combination of measures.

Additionally, the proposal will align the existing fall-back option to harmonised standards uniformly in Directive 2011/65/EU on restriction of hazardous substances in electrical and electronical equipment, Directive 2013/53/EU on recreational craft and personal watercraft, Directive 2014/29/EU on simple pressure vessels, Directive 2014/30/EU on electromagnetic

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8 Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88, ELI: http://data.europa.eu/eli/dir/2011/65/oj).

9 Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90, ELI: http://data.europa.eu/eli/dir/2013/53/oj).

10 Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 96, 29.3.2014, p. 45, ELI: http://data.europa.eu/eli/dir/2014/29/oj).

11 Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79, ELI: http://data.europa.eu/eli/dir/2014/30/oj).

12 Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96, 29.3.2014, p. 107, ELI: http://data.europa.eu/eli/dir/2014/31/oj).

13 Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (OJ L 96, 29.3.2014, p. 149, ELI: http://data.europa.eu/eli/dir/2014/32/oj).

14 Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251, ELI: http://data.europa.eu/eli/dir/2014/33/oj).

15 Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309, ELI: http://data.europa.eu/eli/dir/2014/34/oj).

16 Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357, ELI: http://data.europa.eu/eli/dir/2014/35/oj).

17 Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62, ELI: http://data.europa.eu/eli/dir/2014/53/oj).

18 Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164, ELI: http://data.europa.eu/eli/dir/2014/68/oj).

19 Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146, ELI: http://data.europa.eu/eli/dir/2014/90/oj).

compatibility, Directive 2014/31/EU on non-automatic weighing instruments, Directive 2014/32/EU on measuring instruments, Directive 2014/33/EU on lifts, Directive 2014/34/EU on ATEX, Directive 2014/35/EU on low voltage, Directive 2014/53/EU on radio equipment, and Directive 2014/68/EU on pressure equipment.

To avoid inconsistencies and an additional burden on manufacturers and to create an overall coherence between harmonised product laws under the NLF, it is necessary to introduce a provision that allows for the use of the DPP's data carrier when such DPP is made mandatory by another piece of legislation that covers the same product.

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

The proposal is part of a package of measures concerning simplification. It represents a step in a continuous process of looking comprehensively at existing reporting requirements, with a view to assessing their continued relevance and to making them more efficient.

The rationalisation introduced by these measures will not affect achievement of the objectives in the policy area, for the following reasons:

- The essential information required to ensure compliance with EU legislation will continue to be made available to the relevant authorities and to end-users.

- The increased efficiency of reporting procedures will facilitate the digitalisation of business-to-authority reporting, reduce the administrative burden on businesses and enhancing the overall effectiveness of the regulatory framework.

- The measures will also promote a more consistent and harmonised approach to economic operators' obligations across different EU laws, reducing confusion and facilitating compliance for businesses operating in multiple policy areas.

- Furthermore, in cases where harmonised standards are not available, common specifications will be accepted, ensuring consistency with existing legislative provisions in certain sectoral policy area and providing flexibility for businesses to demonstrate compliance.

- **Consistency with other Union policies**

Under the Regulatory Fitness and Performance Programme (REFIT), the Commission ensures that its legislation is fit for purpose, is tailored to the needs of stakeholders and minimises burdens while achieving its objectives. This proposal is therefore part of the REFIT programme aimed at reducing reporting burdens arising from Union legislation.

While certain obligations are essential, they need to be as efficient as possible, avoiding overlaps, removing unnecessary burdens and using digital and interoperable solutions as much as possible.

The current proposals rationalise reporting requirements thus making the achievement of the objectives of legislations more efficient and less burdensome for companies and public authorities.

In situations where harmonised standards are not available, alternative solutions are necessary to ensure compliance with Union legislation. These alternatives should be as effective as possible, minimising unnecessary complexity and available within short deadlines.

The introduction of these alternative solutions will streamline compliance with Union legislation, making it more efficient and less burdensome for companies and public authorities.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union, in line with the original legal bases for the adoption of the sectoral frameworks, which this proposal aims to amend. These sectoral frameworks are Directive 2000/14/EC on the noise emission in the environment by equipment for use outdoors, Directive 2011/65/EU on restriction of hazardous substances in electrical and electronic equipment, Directive 2013/53/EU on recreational craft and personal watercraft, Directive 2014/29/EU on simple pressure vessels, Directive 2014/30/EU on electromagnetic compatibility, Directive 2014/31/EU on non-automatic weighing instruments, Directive 2014/32/EU on measuring instruments, Directive 2014/33/EU on lifts and safety components for lifts, Directive 2014/34/EU on equipment and protective systems intended for use in potentially explosive atmospheres, Directive 2014/35/EU on electrical equipment designed for use within certain voltage limits, Directive 2014/53/EU on radio equipment, Directive 2014/68/EU on pressure equipment and Directive 2014/90/EU on marine equipment.

The Union sectoral frameworks laid down by the above-mentioned Directives are so-called "product harmonisation legislation". They lay down harmonised rules regarding the design, manufacture, conformity assessment and placing on the market of products. Essentially, these sectoral frameworks introduce for each respective sector/product category the essential requirements of public interest, which the products should meet and the procedures on how to assess the compliance with these requirements.

Another common feature of these frameworks is that they are more or less closely aligned to the general principles and reference provision laid down in the NLF. The NLF for EU product legislation consists of two legal acts adopted in 2008, which are Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products[20] laying down reference provisions for the drawing up of Union legislation harmonising the conditions for the marketing of products, and Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products[21], which sets out the principles of the CE marking and accreditations of conformity assessment bodies.

Thanks to the NLF, all the above-mentioned pieces of legislation affected by this proposal contain provisions of a similar type. The legislative acts in question are aligned with the NLF, with the exception of Directive 2000/14/EC, share a common structure and contain provisions based on the same model. Hence, the obligations of economic operators, provisions concerning notified conformity assessment bodies, accreditation, and CE marking are

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20 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 (OJ L 218, 13.8.2008, p. 82, ELI: http://data.europa.eu/eli/dec/2008/768(1)/oj).

21 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 (OJ L 218, 13.8.2008, p. 30, ELI: http://data.europa.eu/eli/reg/2008/765/oj).

identical or very similar in all these legislative acts. This uniformity facilitates familiarity with the various legislative instruments, particularly for businesses that manufacture or distribute products subject to multiple EU legislative acts. The consistency of these elements enables economic operators to more easily navigate the regulatory landscape, thereby reducing complexity and promoting compliance. However, given that the model provisions were established in 2008, certain aspects of the obligations have, become redundant or obsolete over time, necessitating a review and update to ensure their continued relevance and effectiveness.

The marine equipment sector has unique requirements for ensuring safety on board EU ships, which are reflected in Directive 2014/90/EU. As a result, this Directive has specific rules that differ from other legislation aligned with the NLF. One such rule is the requirement for a paper copy of the declaration of conformity to be kept on board an EU ship until the marine equipment is removed. However, the European Maritime Safety Agency's database available to Member State flag states and market surveillance authorities is suitable for electronic interaction and requires the adaptation of this requirement to the digital age. By uploading a copy of the declaration of conformity to this database, the necessary checks and controls of the marine equipment on the ship can be carried out electronically. This approach will also help ensure uniform application and practices under this legislation, streamlining the process and reducing administrative burdens.

Amending the above-mentioned Directives in the proposed manner, i.e. removing paper-based obligations and transitioning to digital equivalents, will contribute to the digitalisation of business-to-authority reporting, facilitate the digitalisation of and economic operators' obligations and reporting procedures, and enhance the overall efficiency and effectiveness of the regulatory framework.

- **Subsidiarity (for non-exclusive competence)**

The reporting requirements and economic operators' obligations concerned are imposed by Union law and can therefore only be amended at Union level. Member States, companies and consumers will benefit from the removal of references to paper format and the digitalisation of the EU declaration of conformity for economic operators that is the subject of this proposal.

- **Proportionality**

The rationalisation and digitalisation of reporting requirements and economic operators' obligations simplify the legal framework by introducing minimum changes to existing requirements that do not affect the substance of the wider policy objective. The proposal is therefore limited to those changes that are necessary to ensure efficiency without changing any of the substantial elements of the legislation concerned.

The amendments introduce minimal changes to existing requirements, focusing solely on the removal of paper-based references and the digitalisation of the EU declaration of conformity and instructions. By limiting the proposal to these necessary changes, the Commission ensures that the amendments are proportionate to the objectives pursued and do not compromise achievement of the policy goals.

Common specifications as a fall-back option to harmonised standards simplify the legal framework by ensuring consistency in the internal market in the absence of available harmonised standards. The proposal is therefore limited to those changes that are necessary to

ensure efficiency without changing any of the substantial elements of the legislation concerned.

The amendments introduce minimal changes to existing legislation, focusing solely on aligning common specifications in internal market legislation. By limiting the proposal to these necessary changes, the Commission ensures that the amendments are proportionate to the objectives pursued and do not compromise achievement of the policy goals.

- **Choice of the instrument**

All the directives to be amended by this act, namely Directive 2000/14/EC on the noise emission in the environment by equipment for use outdoors, Directive 2011/65/EU on restriction of hazardous substances in electrical and electronic equipment, Directive 2013/53/EU on recreational crafts Directive 2014/29/EU on simple pressure vessels, Directive 2014/30/EU on electromagnetic compatibility, Directive 2014/31/EU on non-automatic weighing instruments, Directive 2014/32/EU on measuring instruments, Directive 2014/33/EU on lifts and safety components for lifts, Directive 2014/34/EU on equipment and protective systems intended for use in potentially explosive atmospheres, Directive 2014/35/EU on electrical equipment designed for use within certain voltage limits, Directive 2014/53/EU on radio equipment, Directive 2014/68/EU on pressure equipment and Directive 2014/90/EU on marine equipment are harmonised pieces of product legislation under the Single Market rules, and most of them are aligned with the NLF.

The Evaluation of the NLF, published in November 2022, revealed that the NLF has successfully harmonised EU product legislation, resulting in a more coherent framework that has reduced burdens and generated cost savings for both businesses and authorities since 2008. However, the evaluation also highlighted that the NLF's outdated requirements, such as paper-based documentation and correspondence, hinder its ability to keep pace with digitalisation and meet modern expectations.

The directives to be amended by this act as regards alignment of common specifications provision, namely Directive 2000/14/EC on the noise emission in the environment by equipment for use outdoors, Directive 2011/65/EU on restriction of hazardous substances in electrical and electronic equipment, Directive 2013/53/EU on recreational crafts, Directive 2014/29/EU on simple pressure vessels, Directive 2014/30/EU on electromagnetic compatibility, Directive 2014/31/EU on non-automatic weighing instruments, Directive 2014/32/EU on measuring instruments, Directive 2014/33/EU on lifts and safety components for lifts, Directive 2014/34/EU on equipment and protective systems intended for use in potentially explosive atmospheres, Directive 2014/35/EU on electrical equipment designed for use within certain voltage limits, Directive 2014/53/EU on radio equipment, Directive 2014/68/EU on pressure equipment and Directive 2014/90/EU on marine equipment, are harmonised pieces of product legislation under the single market rules, and contain the concept of harmonised standards and presumption of conformity.

In conclusion, this omnibus proposal is considered appropriate and efficient due to its ability to adapt the concerned legislation concerned to future needs and remain relevant by allowing for the removal of outdated references, such as to paper formats.

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

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

N/A

- **Stakeholder consultations**

On 14 April 2025, the Commission organised an outreach event in the context of the Industrial Forum Task Force 1.

Members States, industry associations, manufacturers and consumer associations were invited to attend and to give their opinions on the digitalisation of reporting and manufacturer's obligations. In particular, they were asked whether they believed providing the declaration of conformity and the instructions in electronic form would be seen as a burden reduction.

Answers received during the outreach event show that stakeholders are largely in favour of digitalisation as a form of burden reduction, with the vast majority of respondents indicating they consider digitalisation as an effective way of reducing burden. Moreover, the majority of respondents indicated that they consider the digital declaration of conformity and the option to provide digital instructions of use as a burden reduction tool. As regards digital instructions, the majority of respondents expressed a preference for voluntary digital instructions (only if the manufacturer decides on this option).

In parallel, a written consultation has been conducted via the same forum to gather stakeholders' opinions and any data on cost saving that this initiative could bring. The majority of respondents indicated they were in favour of digitalisation, including the digital declaration of conformity and digital instructions.

- **Collection and use of expertise**

The proposed simplification measures were identified following a process of internal scrutiny of existing reporting obligations and based on the experience gained from implementation of the related legislation. Since this is a step in the process of continuous assessment of reporting requirements arising from Union legislation, the scrutiny of such burden and of its impact on stakeholders will continue.

- **Impact assessment**

The proposal concerns limited and targeted changes of legislation with a view of simplifying reporting requirements and ensuring the digitalisation and alignment of common specifications. They are based on experience gained from implementing legislation. The changes do not have significant impact on the policy, but only ensure a more efficient and effective implementation also through aligning common specifications with standing legislation.

- **Regulatory fitness and simplification**

This is a REFIT proposal, aiming to simplify legislation and cut burdens for stakeholders.

- **Fundamental rights**

N/A

4. BUDGETARY IMPLICATIONS

N/A

5. OTHER ELEMENTS

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

N/A

- **Explanatory documents (for directives)**

Considering the scope of the proposal, it is not justified or proportional to require explanatory documents.

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

This proposal includes:

- Specifying that the EU declaration of conformity, or a similar document, must be drawn up in electronic form and made accessible through an internet address or machine-readable code when that declaration needs to accompany a product;
- The addition of a 'digital contact' as information to be indicated by manufacturers on products placed on the market to facilitate communication between economic operators and national authorities. Once the European Business Wallet is available, the digital address it provides to economic operators could constitute the "digital contact";
- Specifying that the instructions accompanying products may be provided in electronic form with the exception of safety information which should be provided on paper or marked on the product for consumers;
- The amendment of reporting obligations to national authorities that require a 'paper or electronic format' to 'electronic form' only;
- The insertion of an obligation for exchanges by electronic means between the economic operators and competent authorities;
- The introduction of a provision on common specifications as an alternative to harmonised standards;
- An obligation to provide the information contained in the EU declaration of conformity and instructions on the digital product passport when the product is subject to another Union legislation that requires the use of such a digital product passport.

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amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications

(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 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,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Reporting requirements play a key role in ensuring proper monitoring and correct enforcement of legislation. However, in order to ensure that they fulfil the purpose for which they were intended and to limit the administrative burden, it is important to streamline those requirements.

(2) In its Communication on ‘Long-term competitiveness of the EU: looking beyond 2030’, the Commission has committed to rationalise and simplify reporting requirements, with the aim to reduce such burdens by 25%, without undermining the related policy objectives.

(3) In its Better Regulation Guidelines, the Commission promotes the ‘digital by default’ principle to support digital transformations by facilitating digital-ready policies which consider the fast-evolving world of digitalisation and technology, and which are digital, interoperable, future-proof and agile by default.

(4) The increasing importance of digitalisation in simplifying regulatory frameworks necessitates the reduction and modernisation of reporting requirements and economic operators’ obligations. In line with the efforts to accelerate digitalisation, it is essential to fully digitalise business-to-authority reporting and economic operators’ obligations when they do not affect protection and safety of consumers. Embracing digitalisation will not only simplify compliance procedures but also enhance the overall efficiency of the regulatory framework, ultimately benefiting both businesses and authorities alike.

(5) A number of sectoral Union legal acts lay down harmonised rules regarding the obligations of economic operators when placing a product on the market or putting it

into service. Such legal acts include Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council ('the Directives concerned'). Most of the Directives are based on the principles of the 'new approach' to technical harmonisation and are also aligned to the reference provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council.

(6) In accordance with the Directives concerned, manufacturers are to draw up an EU declaration of conformity stating that the fulfilment of essential requirements set out in the applicable Directives has been demonstrated. In order to enable seamless electronic processes, the EU declaration of conformity should be drawn up only in electronic form.

(7) Moreover, Directives 2000/14/EC, 2013/53/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU and 2014/53/EU require that a copy of the EU declaration of conformity accompanies the product. Considering the evolution of digitalisation, it is essential to modernise this obligation by requiring that such EU declaration of conformity accompany the product in electronic form. The manufacturer should therefore make sure that the EU declaration of conformity is accessible through an internet address or a machine-readable code.

(8) Taking into account that in 2024 no less than 94% of EU households had access to internet, the paper format of the instructions for use accompanying the products under the scope of the Directives concerned is outdated and is not aligned with the current technologies, the practice of consumers nor with green objectives. Consequently, the possibility for a digital format of the instructions should be introduced in the Directives. This will allow manufacturers to instructions in digital format, if they wish to do so. Where manufacturers choose to provide instructions in digital format, in order to still protect the safety of consumers, the safety information, including instructions having impact on product safety, should be provided in paper format or marked on the product. Moreover, end-users should be able to obtain a paper copy of the instructions for use or safety information, upon request – at the time of the purchase and for a certain period of time after their purchase.

(9) Directive 2014/53/EU provides for the possibility for manufacturers to provide a simplified EU declaration of conformity in an electronic form. Considering that this proposal is introducing a digital by default format of the EU declaration of conformity, the provisions on the simplified EU declaration of Conformity become redundant. It is therefore necessary to remove such provisions from Directive 2014/53/EU.

(10) In order to facilitate communication between economic operators and national competent authorities and end-users, the indication of a digital contact of the manufacturer on the product and in the EU declaration of conformity is necessary to enhance the effectiveness of market surveillance and to expedite the process of tracing non-compliant products. Currently, economic operators are required to indicate their postal address on the product, but this is not always sufficient to ensure that competent authorities can establish rapid contact. It is therefore necessary to require economic operators to provide both a postal address and a digital contact on the product and in the EU declaration of conformity. Such digital contact should be defined in the Directives.

(11) The Directives concerned require that economic operators provide, on a reasoned request from a competent national authority or the European Commission, all

information and documentation necessary to demonstrate the conformity of the concerned products with the respective Directives, in paper or electronic form. The paper-based form is an outdated requirement, while electronic communication enhances interaction between authorities and businesses, streamlining processes and reducing administrative burdens. In order to achieve the digitalisation of reporting requirements and to reduce administrative burden for economic operators and competent authorities, the economic operators should be required to provide the necessary information and documentation in electronic form only. Documentation provided in electronic form could be made available, for example, in a digital printable format, which allows the possibility to print, download and save the documentation on an electronic device.

(12) Directive 2014/90/EU contains certain sectoral specificities, including the unique requirements for ensuring the safety of marine equipment on board EU ships. Due to those specificities, that Directive differs from other NLF-aligned legislation. Specifically, it foresees the obligation for a paper copy of the declaration of conformity to be on board an EU ship until the marine equipment is removed. However, given the availability of the European Maritime Safety Agency''s database to Member State flag states and market surveillance authorities, the obligation should be satisfied by uploading a copy of the declaration of conformity to this database. This would enable the necessary checks and controls of the marine equipment on the ship to be carried out electronically and ensure uniform application and practices under this legislation.

(13) The current Union standardisation framework which is based on Regulation (EU) No 1025/2012 of the European Parliament and of the Council represents the framework by default to elaborate standards that provide for a presumption of conformity with the relevant essential health and safety requirements or with other requirements. However, where no harmonised standards exist or where they are insufficient, the Commission should be able to adopt implementing acts establishing common specifications for the essential health and safety or other requirements, as an exceptional fall-back solution to facilitate the manufacturer’s obligation to comply with those health and safety or other requirements.

(14) As the digital product passport is foreseen in certain Union legislations, such as Regulation (EU) 2023/1542 of the European Parliament and of the Council, it is essential to require the economic operators to store the information contained in the EU declaration of conformity and instructions for use in the digital product passport where a product is covered by multiple pieces of legislation. This approach would reduce the administrative burden on manufacturers, as they would no longer need to maintain separate storage locations for compliance documents. By storing the documentation in one place, all necessary documents demonstrating product compliance would be easily accessible, ensuring transparency and facilitating compliance. This streamlined approach would enhance the overall efficiency of the regulatory framework and aligns with the principle that where several pieces of Union harmonisation legislation apply to a product, the manufacturer or any other economic operator, where appropriate, should provide a single EU declaration of conformity.

(15) Since the objectives of this Directive cannot be sufficiently achieved by the Member States as this Directive amends Directives which are harmonising products legislations but can rather, by reason of harmonisation of EU applicable rules, 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 Directive does not go beyond what is necessary in order to achieve those objectives.

(16) In order to enable economic operators to supply stock of products that have been placed on the market before the date of application of the national measures transposing this Directive, it is necessary to provide for reasonable transitional arrangements that do not impede the making available on the market of products that have been placed on the market in accordance with the Directives concerned before the date of application of the national measures transposing this Directive.

(17) To ensure a smooth and effective transition, to minimize disruptions, and to provide a reasonable timeframe for industries to adjust to the new requirements, application of transposition measures concerning digitalisation should be deferred.

(18) Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2000/14/EC

Directive 2000/14/EC is amended as follows:

(1) in Article 3, the following point (g) is added:

‘(g) ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application.’;

(2) in Article 4(1), the third indent is replaced by the following:

‘the equipment bears CE marking and the indication of the guaranteed sound power level and is accompanied by the internet address or machine-readable code through which the EC declaration of conformity can be accessed.’;

(3) in Article 5, paragraph 1 is replaced by the following:

‘1. Member States shall take appropriate measures to ensure that equipment referred to in Article 2(1) may be placed on the market or put into service only if it conforms to the provisions of this Directive, bears the CE marking and the indication of the guaranteed sound power level and is accompanied by the internet address or machine-readable code through which the EC declaration of conformity can be accessed.’;

(4) in Article 6, paragraph 1 is replaced by the following:

‘1. Member States shall not prohibit, restrict or impede the placing on the market or putting into service in their territory of equipment referred to in Article 2(1) which complies with the provisions of this Directive, bears the CE marking, the indication of the guaranteed sound power level and is accompanied by the internet address or machine-readable code through which the EC declaration of conformity can be accessed.’;

(5) Article 7 is replaced by the following:

‘**Presumption of conformity**

Member States shall presume that equipment referred to in Article 2(1) bearing the CE marking and the indication of the guaranteed sound power level and which is accompanied by

the internet address or machine-readable code through which the EC declaration of conformity can be accessed conforms to all the provisions of this Directive.';

(6) Article 8 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The manufacturer, or his authorised representative established in the Community, of equipment referred to in Article 2(1) shall, in order to certify that an item of equipment is in conformity with the provisions of this Directive, draw up an EC declaration of conformity, in electronic form, for each type of equipment manufactured; the minimum content of this declaration of conformity is laid down in Annex II.';

(b) the following paragraph 4 is added:

'4. Where other Union legislation applicable to the equipment requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EC declaration of conformity or instructions in a digital product passport, the information required in Annex II to be included in the EC declaration of conformity and the instructions referred to in Article 11(5) shall be provided only in that digital product passport.';

(7) Article 14 is amended as follows:

(a) paragraph 3 is replaced by the following:

'3. Member States shall ensure that the Commission and any other Member State may, on a reasoned request, obtain all information, in electronic form, used during the conformity assessment procedure concerning a type of equipment and in particular the technical documentation provided for in Annex V item 3, Annex VI item 3, Annex VII item 2, Annex VIII items 3.1 and 3.3.';

(b) the following paragraph 4 is added:

'4. Where appropriate, the manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.';

(8) Annexes II and V to VIII are amended in accordance with Annex I to this Directive.

Article 2

Amendments to Directive 2011/65/EU

Directive 2011/65/EU is amended as follows:

(1) Article 3 is amended as follows:

(a) the following point (6a) is inserted:

'(6a) 'digital contact' means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application.';

(b) the following point (13a) is inserted:

'(13a) 'common specifications' means a set of technical requirements, other than a standard, that provides means of complying with the requirements applicable to a product, device, service, process or system;';

(2) Article 7 is amended as follows:

(a) in point (c), the first sentence is replaced by the following:

‘(c) Where compliance of EEE with the applicable requirements has been demonstrated by the procedure referred to in point (b), manufacturers draw up an EU declaration of conformity, in electronic form, and affix the CE marking on the finished product.’;

(b) in point (e), the second sentence is replaced by the following:

‘Changes in product design or characteristics and changes in the harmonised standards, in the common specifications or in technical specifications by reference to which conformity of EEE is declared shall be adequately taken into account;’;

(c) point (h) is replaced by the following:

‘(h) manufacturers indicate their name, registered trade name or registered trademark as well as their postal address and digital contact on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. The postal address and digital contact must indicate a single point through which the manufacturer can be reached. Where other applicable Union legislation contains provisions for the affixing of the manufacturer’s name, postal address and digital contact which are at least as stringent, those provisions shall apply;’;

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

‘(j) manufacturers, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EEE with this Directive, in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market.’;

(3) in Article 8, point (b), the second indent is replaced by the following:

‘ further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an EEE with this Directive,’;

(4) Article 9 is amended as follows:

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

‘(d) importers indicate their name, registered trade name or registered trademark as well as their postal address and digital contact on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. Where other applicable Union legislation contains provisions for the affixing of the importer’s name, postal address and digital contact which are at least as stringent, those provisions shall apply.’;

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

‘(h) importers, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in electronic form, necessary to demonstrate the conformity of an EEE with this Directive in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market.’;

(5) in Article 10, point (d) is replaced by the following:

‘(d) distributors, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of EEE with this Directive, and that they cooperate with that authority, at its

request, on any action taken to ensure the compliance with this Directive of the EEE which they have made available on the market.';

(6) in Article 13, the following paragraph 4 is added:

'4. Where other Union legislation applicable to EEE requires the economic operator to include the information that the product complies with the requirement set out in that legislation in a digital product passport or to upload the declaration of conformity in a digital product passport, the information required in Annex VI to be included in the EU declaration of conformity shall be provided only in that digital product passport.';

(7) The following Article 16a is inserted:

'Article 16a

Common Specifications

1. The Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set out in Article 4 in any of the following cases:

(a) requirements set out in Article 4 are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*;
(b) requirements set out in Article 4 are covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, but application of those standards or parts thereof results in non-compliance of materials, components and EEE with the essential requirements set out in Article 4;
(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant materials, components and EEE.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 19(3).

2. Materials, components and EEE that are in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Article 4.';

(8) in Article 19, the following paragraph 3 is added:

'3. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.';

(9) Annexes V and VI are amended in accordance with Annex II to this Directive.

Article 3

Amendments to Directive 2013/53/EU

Directive 2013/53/EU is amended as follows:

(1) Article 3 is amended as follows:

(a) the following point (19a) is inserted:

'(19a) 'digital contact' means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;';

(b) The following point (20a) is inserted:

‘(20a) ‘common specifications’ means a set of technical requirements, other than a standard, that provide means of complying with the essential requirements applicable to a product, device, service, process or system;’;

(2) Article 7 is amended as follows:

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

‘Where compliance of a product with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up a declaration referred to in Article 15, in electronic form, and mark and affix the CE marking, as set out in Articles 17 and 18.’;

(b) in paragraph 4, the second sentence is replaced by the following:

‘Changes in product design or characteristics and changes in the harmonised standards or common specifications by reference to which conformity of a product is declared shall be adequately taken into account.’;

(c) paragraphs 6 and 7 are replaced by the following:

‘6. Manufacturers shall indicate their name, registered trade name or registered trademark as well as their postal address and digital contact on the product or, where that is not possible, on its packaging or in a document accompanying the product. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’;

7. Manufacturers shall ensure that the product is accompanied by instructions and safety information in the owner’s manual in a language or languages which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and safety information may be provided in electronic form.

The manufacturer shall take into account the intended use and the foreseeable end-user of the product when deciding the specific format for the instructions and safety information.

In the case of product intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the product, the safety information. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

(a) mark on the product, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the product; this requirement also applies where the instructions are embedded in the software of the product;

(c) make them accessible online during the expected lifetime of the product and for at least 10 years after the placing on the market of the product.

However, the end-user may, at time of the purchase of the product, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-

user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.';

(d) in paragraph 9, the first sentence is replaced by the following:

'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the product, in a language which can be easily understood by that authority.';

(3) in Article 8(3), point (b) is replaced by the following:

'(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product;';

(4) Article 9 is amended as follows:

(a) paragraph 3 is replaced by the following:

'3. Importers shall indicate their name, registered trade name or registered trademark as well as their postal address and digital contact on the product or, in the case of components where that is not possible, on the packaging or in a document accompanying the product.';

(b) in paragraph 9, the first sentence is replaced by the following:

'Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the product, in a language which can be easily understood by that authority.';

(5) in Article 10(5), the first sentence is replaced by the following:

'Distributors shall, further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the product.';

(6) the following Article 14a is inserted:

'Article 14a

Common Specifications

1. The Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set out in Article 4 in any of the following cases:

(a) requirements set out in Article 4 are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*;
(b) requirements set out in Article 4 are covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, but application of those standards or parts thereof results in non-compliance of products with the essential requirements set out in Article 4; or
(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant products.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 50(2).

2. Products that are in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Article 4.';

(7) Article 15 is amended as follows:

(a) in paragraph 4, the introductory sentence is replaced by the following:

'The following products, when made available on the market or put into service, shall be accompanied by the internet address of machine-readable code through which the EU declaration of conformity, referred to in paragraph 3, can be accessed:';

(b) the following paragraph 6 is added:

'6. Where other Union legislation applicable to the product requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex IV to be included in the EU declaration of conformity and the instructions referred to in Article 7(7) shall be provided only in the digital product passport.';

(8) in Article 19, the following paragraph 5 is added:

'5. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to the conformity assessment procedures in electronic form.';

(9) in Article 20(1), point (b)(i), the indents are replaced by the following:

'where the harmonised standards or common specifications relating to points 3.2 and 3.3 of Part A of Annex I are complied with: Module A (internal production control), Module A1 (internal production control plus supervised product testing), Module B (EU type-examination) together with Module C, D, E or F, Module G (conformity based on unit verification) or Module H (conformity based on full quality assurance);

— where the harmonised standards or common specifications relating to points 3.2 and 3.3 of Part A of Annex I are not complied with: Module A1 (internal production control plus supervised product testing), Module B (EU type-examination) together with Module C, D, E or F, Module G (conformity based on unit verification) or Module H (conformity based on full quality assurance);';

(10) Article 21 is amended as follows:

(a) in point (a), the introductory sentence is replaced by the following:

'where tests are conducted using the harmonised standard or common specification, any of the following modules:';

(b) in point (b), the introductory sentence is replaced by the following:

'where tests are conducted without using the harmonised standard or common specification, any of the following modules:';

(11) Article 22 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in point (a), the introductory sentence is replaced by the following:

'where tests are conducted using the harmonised standard or common specification for noise measurement, any of the following modules:';

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

‘(b) Where tests are conducted without using the harmonised standard or common specification for noise measurement, Module G (conformity based on unit verification).’;

(b) paragraph 2 is amended as follows:

(i) in point (a), the introductory sentence is replaced by the following:

‘Where tests are conducted using the harmonised standard or common specification for noise measurement, any of the following modules:’;

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

‘(b) Where tests are conducted without using the harmonised standard or common specification for noise measurement, Module G (conformity based on unit verification).’;

(12) in Article 30(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential requirements, the applicable harmonised standards or common specifications, the relevant Union harmonisation legislation and the relevant national legislation;’;

(13) in Article 38, paragraph 3 is replaced by the following:

‘3. Where a notified body finds that requirements laid down in Article 4(1) and Annex I or in corresponding harmonised standards or common specifications have not been met by a manufacturer or a private importer, it shall require that manufacturer or private importer to take appropriate corrective measures and shall not issue a conformity certificate.’;

(14) Annexes I, III, IV and V are amended in accordance with Annex III to this Directive.

Article 4

Amendments to Directive 2014/29/EU

Directive 2014/29/EU is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (7a) is inserted:

‘(7a) ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;’;

(b) the following point (9a) is inserted:

‘(9a) ‘common specifications’ means a set of technical requirements, other than a standard, that provide means of complying with the essential requirements applicable to a product, device, service, process or system;’;

(2) Article 6 is amended as follows:

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

‘Where compliance of a vessel of which the product of PS × V exceeds 50 bar.L with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking and the inscriptions provided for in point 1 of Annex III.’;

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

‘Changes in vessels design or characteristics and changes in the harmonised standards, in the common specifications or in other technical specifications by reference to which conformity of a vessel is declared shall be adequately taken into account.’;

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the vessel their name, registered trade name or registered trademark as well as their postal address and digital contact. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’;

(d) paragraph 7 is replaced by the following:

‘7. Manufacturers shall ensure that the vessel is accompanied by the instructions and safety information referred to in point 2 of Annex III in a language which can be easily understood by end-users, as determined by the Member State concerned. The instructions and safety information referred to in point 2 of Annex III may be provided in electronic form. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the vessel when deciding the specific format for the instructions and safety information.

In the case of vessel for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the vessel, the safety information referred to in point 2 of Annex III. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

(a) mark on the vessel, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the vessel; this requirement also applies where the instructions are embedded in the software of the vessel;

(c) make them accessible online during the expected lifetime of the vessel and for at least 10 years after the placing on the market of the vessel.

However, the end-user may, at time of the purchase of the vessel, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.’;

(e) in paragraph 9, the first sentence, is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to

demonstrate the conformity of the vessel with this Directive, in a language which can be easily understood by that authority.';

(3) in Article 7(2), point (b) is replaced by the following:

'(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a vessel;';

(4) Article 8 is amended as follows:

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

'Importers shall indicate on the vessel their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, in a document accompanying the vessel.';

(b) in paragraph 9, the first sentence is replaced by the following:

'Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a vessel in a language which can be easily understood by that authority.';

(5) in Article 9(5), the first sentence is replaced by the following:

'Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a vessel.';

(6) the following Article 12a is inserted:

'Article 12a

Common Specifications

1. The Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set out in Annex I in any of the following cases:

(a) requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*;

(b) requirements set out in Annex I are covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, but application of those standards or parts thereof results in non-compliance of vessels of which the product of PS × V exceeds 50 bar.L with the essential requirements set out in Article 4; or

(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant vessels of which the product of PS × V exceeds 50 bar.L.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 39(2).

2. Vessels of which the product of PS × V exceeds 50 bar.L that are in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Annex I.';

(7) Article 13 is amended as follows

(a) paragraph 1 is amended as follows:

(i) in point (a), the introductory sentence is replaced by the following:

‘(a) for vessels manufactured in accordance with the harmonised standards referred to in Article 12 or common specifications referred to in Article 12a, at the choice of the manufacturer, in either of the following two manners:’;

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

‘(b) for vessels not manufactured, or manufactured only partly, in accordance with the harmonised standards referred to in Article 12, or the common specifications referred to in Article 12a, the manufacturer shall submit for examination a prototype, representative of the production envisaged, of the complete vessel and the technical documentation and supporting evidence for examination and assessment of the adequacy of the technical design of the vessel (Module B – production type).’;

(b) paragraph 3 is replaced by the following:

‘3. The records and correspondence relating to the conformity assessment procedures referred to in paragraphs 1 and 2 shall be drawn up, in electronic form, in an official language of the Member State in which the notified body is established or in a language accepted by that body.’;

(c) the following paragraph 4 is added:

‘4. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.’;

(8) in Article 14, the following paragraph 5 is added:

‘5. Where other Union legislation applicable to the vessel requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex IV to be included in the EU declaration of conformity and the instructions referred to in Article 6(7) shall be provided only in that digital product passport.’;

(9) in Article 21(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;’;

(10) in Article 29, paragraph 3 is replaced by the following:

‘3. Where a notified body finds that the essential safety requirements set out in Annex I or corresponding harmonised standards, or common specifications, or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.’;

(11) Annexes II, III and IV are amended in accordance with Annex IV to this Directive.

Article 5

Amendments to Directive 2014/30/EU

Directive 2014/30/EU is amended as follows:

(1) Article 3 is amended as follows:

(a) the following point (15a) is inserted:

‘(15a) ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;’;

(b) the following point (17a) is inserted:

‘(17a) ‘common specifications’ means a set of technical requirements, other than a standard, that provide means of complying with the essential requirements applicable to a product, device, service, process or system;’;

(2) Article 7 is amended as follows:

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

‘Where compliance of apparatus with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.’;

(b) in paragraph 4, the second sentence is replaced by the following:

‘Changes in apparatus design or characteristics and changes in the harmonised standards, in the common specifications, or in other technical specifications by reference to which conformity of apparatus is declared shall be adequately taken into account.’;

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate, on the apparatus, their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the apparatus. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’;

(d) paragraph 7 is replaced by the following:

‘7. Manufacturers shall ensure that the apparatus is accompanied by instructions and the information referred to in Article 18, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and information referred to in Article 18 may be provided in electronic form. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

In the case of apparatus intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the apparatus, the information referred to in Article 18. Such information shall be easily visible and legible for consumers.

When drafting the information referred to in Article 18, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

(a) mark on the apparatus, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the apparatus;

(c) make them accessible online during the expected lifetime of the apparatus and for at least 10 years after the placing on the market of the apparatus.

However, the end-user may, at time of the purchase of the apparatus, or up to six months after that purchase, request the instructions or information referred to in Article 18 in paper format. Where the end-user requests those instructions or information referred to in Article 18, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.';

(e) in paragraph 9, the first sentence is replaced by the following:

'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the apparatus with this Directive, in a language which can be easily understood by that authority.';

(3) in Article 8(2), point (b) is replaced by the following:

'(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the apparatus;';

(4) Article 9 is amended as follows:

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

'Importers shall indicate on the apparatus their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the apparatus.';

(b) in paragraph 8, the first sentence is replaced by the following:

'Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of apparatus in a language which can be easily understood by that authority.';

(5) in Article 10(5), the first sentence is replaced by the following:

'Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the apparatus.';

(6) the following Article 13a is inserted:

'Article 13a

Common Specifications

1. The Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set out in Annex I in any of the following cases:

(a) requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*;

(b) requirements set out in Annex I are covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, but application of those standards or parts thereof results in non-compliance of equipment with the essential requirements set out in Annex I; or

(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant equipment.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 41(2).

2. Apparatus that is in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Annex I.';

(7) in Article 14, the following subparagraph is added:

'The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedure in electronic form.';

(8) in Article 15, the following paragraph 5 is added:

'5. Where other Union legislation applicable to an apparatus requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex IV to be included in the EU declaration of conformity and the instructions referred to in Article 7(7) shall be provided only in that digital product passport.';

(9) in Article 24(7), point (c) is replaced by the following:

'(c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;';

(10) in Article 32, paragraph 3 is replaced by the following:

'3. Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate.';

(11) Annexes II, III and IV are amended in accordance with Annex V to this Directive.

Article 6

Amendments to Directive 2014/31/EU

Directive 2014/31/EU is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (9a) is inserted:

'(9a) 'digital contact' means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;';

(b) the following point (11a) is inserted:

‘(11a) ‘common specifications’ means a set of technical requirements, other than a standard, that provide means of complying with the essential requirements applicable to a product, device, service, process or system;’;

(2) Article 6 is amended as follows:

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

‘Where compliance of an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) with the applicable requirements has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking and the supplementary metrology marking.’;

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

‘Changes in instrument design or characteristics and changes in the harmonised standards, in the common specifications, or in other technical specifications by reference to which conformity of an instrument is declared shall be adequately taken into account.’;

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the instrument their name, registered trade name or registered trademark as well as their postal address and digital contact. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’;

(d) paragraph 7 is replaced by the following:

‘7. Manufacturers shall ensure that the instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is accompanied by instructions and information in a language which can be easily understood by end-users, as determined by the Member State concerned. The instructions and information may be provided in electronic form. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the product when deciding the specific format for the instructions and information.

In the case of an instrument intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide in paper format, or mark on the product, the information that is essential for using it in a safe way. Such information shall be easily visible and legible for consumers.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

(a) mark on the instrument, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the instrument; this requirement also applies where the instructions are embedded in the software of the instrument;

(c) make them accessible online during the expected lifetime of the instrument and for at least 10 years after the placing on the market of the instrument.

However, the end-user may, at time of the purchase of the instrument, or up to six months after that purchase, request the instructions and information in paper format. Where the end-

user requests those instructions and information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.';

(e) in paragraph 9, the first sentence is replaced by the following:

'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the instrument with this Directive, in a language which can be easily understood by that authority.';

(3) in Article 7(2), point (b) is replaced by the following:

'(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an instrument;';

(4) Article 8 is amended as follows:

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

'Importers shall indicate on the instrument their name, registered trade name or registered trademark as well as their postal address and digital contact.';

(b) in paragraph 9, the first sentence is replaced by the following:

'Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an instrument in a language which can be easily understood by that authority.';

(5) in Article 9(5), the first sentence is replaced by the following:

'Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an instrument.';

(6) the following Article 12a is inserted:

'Article 12a

Common Specifications

1. The Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set out in Annex I in any of the following cases:

(a) requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*;

(b) requirements set out in Annex I are covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, but application of those standards or parts thereof results in non-compliance of instruments with the essential requirements set out in Annex I; or

(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant instruments.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 41(2).

2. Instruments that are in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Annex I.';

(7) in Article 13, paragraph (2 is replaced by the following:

'2. The documents and correspondence relating to the conformity assessment procedures referred to in paragraph 1 shall be drawn up, in electronic form, in one of the official languages of the Member State where those procedures are carried out, or in a language accepted by the body notified in accordance with Article 19.';

(8) in Article 14, the following paragraph 5 is added:

'5. Where other Union legislation applicable to an instrument requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex IV to be included in the EU declaration of conformity and instructions referred to in Article 6(7) shall be provided only in that digital product passport.';

(9) in Article 23(7), point (c) is replaced by the following:

'(c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;';

(10) in Article 31, paragraph 3 is replaced by the following:

'3. Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.';

(11) Annexes II and IV are amended in accordance with Annex VI to this Directive.

Article 7

Amendments to Directive 2014/32/EU

Directive 2014/32/EU is amended as follows:

(1) Article 4 is amended as follows:

(a) the following point (12a) is inserted:

'(12a) 'digital contact' means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;';

(b) the following point (14a) is inserted:

'(14a) 'common specifications' means a set of technical requirements, other than a standard, that provide means of complying with the essential requirements applicable to a product, device, service, process or system;';

(2) Article 8 is amended as follows:

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

'Where compliance of a measuring instrument with the applicable requirements of this Directive has been demonstrated by that conformity assessment procedure, manufacturers

shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking and the supplementary metrology marking.';

(b) in paragraph 4, the second sentence is replaced by the following:

'Changes in measuring instrument design or characteristics and changes in the harmonised standards, common specifications, normative documents or in other technical specifications by reference to which conformity of a measuring instrument is declared shall be adequately taken into account.'

(c) paragraph 6, the first and second sentences are replaced by the following:

'Manufacturers shall indicate on the measuring instrument their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, in a document accompanying the measuring instrument and on the packaging, if any, in accordance with point 9.2 of Annex I. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.';

(d) in paragraph 7, the first sentence is replaced by the following:

'7. Manufacturers shall ensure that the measuring instrument which they have placed on the market is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed, and by instructions and information in accordance with point 9.3 of Annex I in a language which can be easily understood by end-users, as determined by the Member State concerned. The instructions and information may be provided in electronic form. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the product when deciding the specific format for the instructions and information in accordance with point 9.3 of Annex I.

In the case of measuring instrument intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the product, the information in accordance with point 9.3 of Annex I. Such information shall be easily visible and legible for consumers.

When drafting the instructions and information in accordance with point 9.3 of Annex I, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions and information play for ensuring safety.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

(a) mark on the measuring instrument, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the measuring instrument; this requirement also applies where the instructions are embedded in the software of the measuring instrument;

(c) make them accessible online during the expected lifetime of the measuring instrument and for at least 10 years after the placing on the market of the measuring instrument.

However, the end-user may, at time of the purchase of the measuring instrument, or up to six months after that purchase, request the instructions and information in accordance with point 9.3 of Annex I in paper format. Where the end-user requests those instructions information in

accordance with point 9.3 of Annex I, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.';

(e) in paragraph 9, the first sentence is replaced by the following:

'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the measuring instrument with this Directive, in a language which can be easily understood by that authority.';

(3) in Article 9(2), point (b) is replaced by the following:

'(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a measuring instrument;';

(4) Article 10 is amended as follows:

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

'They shall ensure that the manufacturer has drawn up the technical documentation, that the measuring instrument bears the CE marking and the supplementary metrology marking and is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and by the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).';

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

'Importers shall indicate on the measuring instrument their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, in a document accompanying the measuring instrument and on its packaging, if any, in accordance with point 9.2 of Annex I.';

(c) in paragraph 9, the first sentence is replaced by the following:

'Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a measuring instrument in a language which can be easily understood by that authority.';

(5) Article 11 is amended as follows:

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

'Before making a measuring instrument available on the market and/or putting a measuring instrument into use distributors shall verify that the measuring instrument bears the CE marking and the supplementary metrology marking, that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed, by the required documents, and by instructions and information in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users in the Member State in which the measuring instrument is to be made available on the market and/or put into use, and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3) respectively.';

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

'Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a measuring instrument.';

(6) the following Article 14a is inserted:

‘Article 14a

Common Specifications

1. The Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those parts of normative documents, in any of the following cases:

(a) requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those parts of normative documents are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*;

(b) requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those parts of normative documents are covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, but application of those standards or parts thereof results in non-compliance of measuring instruments with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those parts of normative documents; or

(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant measuring instruments.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 46(2).

2. Measuring instruments that are in conformity with the common specification shall be presumed to be in conformity with essential requirements set out in Article 6 covered by those common specifications or parts thereof.’;

(7) Article 17 is amended as follows:

(a) the third subparagraph is replaced by the following:

‘Records and correspondence relating to conformity assessment procedures shall be drawn up in electronic form, in the official language(s) of the Member State where the notified body carrying out the conformity assessment procedures is established, or in a language accepted by that body.’;

(b) the following subparagraph is added:

‘The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.’;

(8) in Article 18(3), points (f) and (g) are replaced by the following:

‘(f) a list of the harmonised standards and/or normative documents referred to in Article 14, and/or common specifications referred to in Article 14a applied in full or in part, the references of which have been published in the Official Journal of the European Union;

(g) descriptions of the solutions adopted to meet the essential requirements where the harmonised standards and/or common specification and/or normative documents referred to in Article 14 have not been applied, including a list of the relevant technical specifications applied;’;

(9) in Article 19, the following paragraph 5 is added:

‘5. Where other Union legislation applicable to measuring instruments requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex XIII to be included in the EU declaration of conformity and the instructions referred to in Article 8(7) shall be provided only in that digital product passport.’;

(10) in Article 27(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential requirements set out in Annex I and in the relevant instrument-specific Annexes, of the applicable harmonised standards or common specifications and normative documents and of the relevant provisions of Union harmonisation legislation and of national legislation;’;

(11) in Article 36, paragraph 3 is replaced by the following:

‘3. Where a notified body finds that the essential requirements set out in Annex I and in the relevant instrument-specific Annexes or corresponding harmonised standards, normative documents, common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.’;

(12) in Article 45(1), point (d) is replaced by the following:

‘(d) the measuring instrument is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed;’;

(13) Annexes II and XIII are amended in accordance with Annex VII to this Directive.

Article 8

Amendments to Directive 2014/33/EU

Directive 2014/33/EU is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (11a) is inserted:

‘(11a) ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;’;

(b) the following point (13a) is inserted:

‘(13a) ‘common specifications’ means a set of technical requirements, other than a standard, that provide means of complying with the essential requirements applicable to a product, device, service, process or system;’;

(2) Article 7 is amended as follows:

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

‘Where compliance of the lift with the applicable essential health and safety requirements has been demonstrated by that procedure, the installer shall draw up an EU declaration of conformity, in electronic form, ensure that the lift is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and, affix the CE marking.’;

(b) in paragraph 6, the first and second sentences are replaced by the following:

‘Installers shall indicate, on the lift, their name, registered trade name or registered trademark, as well as their postal address and digital contact. The postal address and digital contact shall indicate a single point through which the installer can be reached.’;

(c) paragraph 7 is replaced by the following:

‘7. Installers shall ensure that the lift is accompanied by the instructions referred to in point 6.2 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State in which the lift is placed on the market. The instructions may be provided in electronic form. Such instructions, as well as any labelling, shall be clear, understandable and intelligible.

When the instructions are provided in electronic form, the installer shall:

(a) mark on the lift, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the lift; this requirement also applies where the instructions are embedded in the software of the lift;

(c) make them accessible online during the expected lifetime of the lift and for at least 10 years after the placing on the market of the lift.

However, the end-user may, at time of the purchase of the lift, or up to six months after that purchase, request the instructions in paper format. Where the end-user requests those instructions, the installer shall provide them to the end-user, free of charge, within one month of receiving the request.’;

(d) in paragraph 9, the first subparagraph is replaced by the following:

‘Installers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the lift with this Directive, in a language which can be easily understood by that authority.’;

(3) Article 8 is amended as follows:

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

‘Where compliance of a safety component for lifts with the applicable essential health and safety requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, ensure that the safety component for lifts is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed, and affix the CE marking.’;

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

‘Changes in product design or characteristics and changes in the harmonised standards, in the common specifications, or in other technical specifications by reference to which conformity of a safety component for lifts is declared shall be adequately taken into account.’;

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the safety component for lifts their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that

is not possible, on the label referred to in Article 19(1). The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.';

(d) paragraph 7 is replaced by the following:

'7. Manufacturers shall ensure that the safety component for lifts is accompanied by the instructions referred to in point 6.1 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned. The instructions may be provided in electronic form. Such instructions, as well as any labelling, shall be clear, understandable and intelligible.

When the instructions are provided in electronic form, the manufacturer shall:

(a) mark on the safety component for lifts, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times; this requirement also applies where the instructions are embedded in the software of the safety component for lifts;

(c) make them accessible online during the expected lifetime of the safety component for lifts and for at least 10 years after the placing on the market of safety component for lifts.

However, the end-user may, at time of the purchase of the safety component for lift, or up to six months after that purchase, request the instructions in paper format. Where the end-user requests those instructions, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.';

(e) in paragraph 9, first subparagraph, the first sentence is replaced the following:

'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the safety components for lifts with this Directive, in a language which can be easily understood by that authority.';

(4) in Article 9(2), point (b) is replaced by the following:

'(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the safety components for lifts or the lift;';

(5) Article 10 is amended as follows:

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

'They shall ensure that the manufacturer has drawn up the technical documentation, that the safety component for lifts bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and by the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).';

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

'Importers shall indicate on the safety component for lifts their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the safety component for lifts.';

(c) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a safety component for lifts in a language which can be easily understood by that authority.’;

(6) Article 11 is amended as follows:

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

‘Before making a safety component for lifts available on the market, distributors shall verify that the safety component for lifts bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed, by the required documents and by the instructions referred to in point 6.1 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3), respectively.’;

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

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a safety component for lifts.’;

(7) the following Article 14a is inserted:

‘Article 14a

Common Specifications

1. The Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set out in Annex I in any of the following cases:

(a) requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the references of which have been published in *the Official Journal of the European Union*;

(b) requirements set out in Annex I are covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, but application of those standards or parts thereof results in non-compliance of lifts and components for lifts with the essential requirements set out in Annex I; or

(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant lifts and components for lifts.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 42(2).

2. Lifts and safety components for lifts that are in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Annex I.’;

(8) in Article 15, the following subparagraph is added:

‘The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures for safety components for lifts in electronic form.’;

(9) in Article 16, the following paragraph 5 is added:

‘5. The installer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures for lifts in electronic form.’;

(10) in Article 17, the following paragraph 5 is added:

‘5. Where other Union legislation applicable to lifts or safety components for lifts requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex II to be included in the EU declaration of conformity and the instructions referred to in Articles 7(7) and 8(7) shall be provided only in that digital product passport.’;

(11) in Article 24(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex I, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of its relevant national legislation;’;

(12) in Article 32, paragraph 3 is replaced by the following:

‘3. Where a notified body finds that the essential health and safety requirements of this Directive or corresponding harmonised standards or common specifications or other technical specifications have not been met by an installer or a manufacturer, it shall require the installer or the manufacturer to take appropriate corrective measures and shall not issue a certificate.’;

(13) in Article 41(1), point (g) is replaced by the following:

‘(g) the name, registered trade name or registered trademark, the postal address and digital contact of the installer, manufacturer or importer has not been indicated in compliance with Article 7(6), Article 8(6) or Article 10(3);’;

(14) Annexes II and IV to XII are amended in accordance with Annex VIII to this Directive.

Article 9

Amendments to Directive 2014/34/EU

Directive 2014/34/EU is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (16a) is inserted:

‘(16a) ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;’;

(b) the following point (18a) is inserted:

‘(18a) ‘common specifications’ means a set of technical requirements, other than a standard, that provide means of complying with the essential requirements applicable to a product, device, service, process or system;’;

(2) Article 6 is amended as follows:

(a) in paragraph 2, the second, third and fourth subparagraphs are replaced by the following:

‘Where compliance of a product, other than a component, with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.

Where compliance of a component with the applicable requirements has been demonstrated by the relevant conformity assessment procedure, manufacturers shall draw up a written attestation of conformity, in electronic form, as referred to in Article 13(3).

Manufacturers shall ensure that each product is accompanied by the internet address or machine-readable code through which the EU declaration of conformity or the attestation of conformity, as appropriate, can be accessed. However, where a large number of products are delivered to a single end-user, the batch or consignment concerned may be accompanied by a single internet address or machine-readable code through which the EU declaration of conformity can be accessed.’;

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

‘Changes in a product design or characteristics and changes in the harmonised standards, in the common specifications, or in other technical specifications by reference to which conformity of a product is declared shall be adequately taken into account.’;

(c) in paragraph 7, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate, on the product, their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the product. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’;

(d) paragraph 8 is replaced by the following:

‘8. Manufacturers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by end-users, as determined by the Member State concerned. The instructions and safety information may be provided in electronic form. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the product when deciding the specific format for the instructions and safety information.

In the case of products intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide in paper format, or mark on the product, the safety information. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

(a) mark on the product, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the product; this requirement also applies where the instructions are embedded in the software of the product;

(c) make them accessible online during the expected lifetime of the product and for at least 10 years after the placing on the market of the product.

However, the end-user may, at time of the purchase of the product, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.';

(e) in paragraph 10, the first sentence is replaced by the following:

'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the product with this Directive, in a language which can be easily understood by that authority.';

(3) in Article 7(2), point (b) is replaced by the following:

'(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product;';

(4) Article 8 is amended as follows:

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

'They shall ensure that the manufacturer has drawn up the technical documentation, that the product bears the CE marking, where applicable, and that it is accompanied by the internet address or machine-readable code where the EU declaration of conformity or the attestation of conformity can be accessed and by the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5), (6) and (7).';

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

'Importers shall indicate on the product their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the product.';

(c) in paragraph 9, the first sentence is replaced by the following:

'Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product in a language which can be easily understood by that authority.';

(5) Article 9 is amended as follows:

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

'Before making a product available on the market distributors shall verify that the product bears the CE marking, where applicable, and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity or the attestation of conformity can be accessed and by the required documents and by instructions and safety information, in a language which can be easily understood by end-users in the Member State in which the product is to be made available on the market, and that the manufacturer and the

importer have complied with the requirements set out in Article 6(5), (6) and (7) and Article 8(3) respectively.';

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

'Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product.';

(6) the following Article 12a is inserted:

'Article 12a

Common Specifications

1. The Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set out in Annex II in any of the following cases:

(a) requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*;

(b) requirements set out in Annex II are covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, but application of those standards or parts thereof results in non-compliance of products with the essential requirements set out in Annex II; or

(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant products.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 39(2).

2. Products that are in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Annex II.';

(7) Article 13 is amended as follows:

(a) paragraph 6 is replaced by the following:

'6. Documents and correspondence relating to the conformity assessment procedures referred to in paragraphs 1 to 4 shall be drawn up, in electronic form, in a language, determined by the Member State concerned.';

(b) the following paragraph 7 is added:

'7. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.';

(8) in Article 14, the following paragraph 5 is added:

'5. Where other Union legislation applicable to a product requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex X to be included in the EU declaration of conformity and the instructions referred to in Article 6(7) shall be provided only in that digital product passport.';

(9) in Article 21(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the applicable harmonised standards or common specifications, of the relevant provisions of Union harmonisation legislation and of national legislation;’ ;

(10) in Article 29, paragraph 3 is replaced by the following:

‘3. Where a notified body finds that the essential health and safety requirements set out in Annex II or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.’;

(11) in Article 38(1), point (e) is replaced by the following:

‘(e) the product is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity or the attestation of conformity, as appropriate, can be accessed;’;

(12) Annexes II to V and VII to X are amended in accordance with Annex IX to this Directive.

Article 10

Amendments to Directive 2014/35/EU

Directive 2014/35/EU is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (7a) is inserted:

‘(7a) ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;’;

(b) the following point (9a) is inserted:

‘(9a) ‘common specifications’ means a set of technical requirements, other than a standard, that provide means of complying with the safety objectives applicable to a product, device, service, process or system;’;

(2) Article 6 is amended as follows:

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

‘Where compliance of electrical equipment with the safety objectives referred to in Article 3 and set out in Annex I has been demonstrated by the conformity assessment procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.’;

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

‘Changes in product design or characteristics and changes in the harmonised standards referred to in Article 12, the common specifications referred to in Article 12a, the international or national standards referred to in Articles 13 and 14, or in other technical specifications by reference to which conformity of electrical equipment is declared shall be adequately taken into account.’;

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the electrical equipment their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the electrical equipment. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’;

(d) paragraph 7 is replaced by the following:

‘7. Manufacturers shall ensure that the electrical equipment is accompanied by instructions and safety information, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and safety information may be provided in electronic form. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the electrical equipment when deciding the specific format for the instructions and safety information.

In the case of electrical equipment intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the product, the safety information. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

(a) mark on the electrical equipment, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the electrical equipment; this requirement also applies where the instructions are embedded in the software of the electrical equipment;

(c) make them accessible online during the expected lifetime of the electrical equipment and for at least 10 years after the placing on the market of the electrical equipment.

However, the end-user may, at time of the purchase of the electrical equipment, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.’;

(e) in paragraph 9, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the electrical equipment with this Directive, in a language which can be easily understood by that authority.’;

(3) in Article 7(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of electrical equipment;’;

(4) Article 8 is amended as follows:

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

‘Importers shall indicate on the electrical equipment their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the electrical equipment.’;

(b) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of electrical equipment in a language which can be easily understood by that authority.’;

(5) in Article 9(5), the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of electrical equipment.’;

(6) the following Article 14a is inserted:

‘Article 14a

Common Specifications

1. The Commission may, by means of implementing acts, adopt common specifications that enable compliance with the safety objectives referred to in Article 3 and set out in Annex I in any of the following cases:

(a) objectives referred to in Article 3 and set out in Annex I are not covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union;

(b) objectives referred to in Article 3 and set out in Annex I are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standards or parts thereof results in non-compliance of electrical equipment with the essential requirements set out in Annex II; or

(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant electrical equipment.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 23(3a).

2. Electrical equipment that are in conformity with the common specification shall be presumed to be in conformity with safety objectives covered by those common specifications or parts thereof, referred to in Article 3 and set out in Annex I.’;

(7) in Article 15, the following paragraph 5 is added:

‘5. Where other Union legislation applicable to electrical equipment requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex IV to be included in the EU declaration of conformity and the instructions referred to in Article 6(7) shall be provided only in that digital product passport.’;

(8) in Article 23, the following paragraph 3a is inserted:

‘3a. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.’;

(9) Annexes III and IV are amended in accordance with Annex X to this Directive.

Article 11

Amendments to Directive 2014/53/EU

Directive 2014/53/EU is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (16a) is inserted:

‘(16a) ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;’;

(b) the following point (18a) is inserted:

‘(18a) ‘common specifications’ means a set of technical requirements, other than a standard, that provide means of complying with the essential requirements applicable to a product, device, service, process or system;’;

(2) Article 10 is amended as follows:

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

‘Where compliance of radio equipment with the applicable requirements has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.’;

(b) in paragraph 5, the second sentence is replaced by the following:

‘Changes in radio equipment design or characteristics and changes in the harmonised standards, or in the common specifications, or in other technical specifications by reference to which conformity of radio equipment is declared shall be adequately taken into account.’;

(c) in paragraph 7, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the radio equipment their name, registered trade name or registered trademark as well as their postal address and digital contact or, where the size or nature of radio equipment does not allow it, on its packaging, or in a document accompanying the radio equipment. The postal address and digital contact shall indicate a single point through which through which the manufacturer can be reached.’;

(d) paragraph 8 is replaced by the following:

‘8. Manufacturers shall ensure that the radio equipment is accompanied by instructions and safety information. The instructions and safety information may be provided in electronic form in accordance with the sixth subparagraph of this paragraph. The manufacturer shall take into account the intended use and the foreseeable end-user of the radio equipment when deciding the specific format for the instructions and safety information. The instructions shall include the information required to use radio equipment in accordance with its intended use. Such information shall include, where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended.

Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

The following information shall also be included in the instructions in the case of radio equipment intentionally emitting radio waves:

(a) frequency band(s) in which the radio equipment operates;

(b) maximum radio-frequency power transmitted in the frequency band(s) in which the radio equipment operates.

In the case of radio equipment referred to in Article 3(4), the instructions shall contain information on the specifications relating to the radio equipment's charging capabilities and the compatible charging devices, as set out in Part II of Annex Ia. In addition to being included in the instructions, when the manufacturers make such radio equipment available to consumers and other end-users, the information shall be also displayed on a label, as set out in Part IV of Annex Ia. The label shall be included in the instructions and printed on the packaging or affixed to the packaging as a sticker. In the absence of packaging, the sticker with the label shall be affixed to the radio equipment. When the radio equipment is made available to consumers and other end-users, the label shall be displayed in a visible and legible manner and, in the case of distance selling, close to the price indication. Where the size or nature of the radio equipment does not allow otherwise, the label may be printed as a separate document accompanying the radio equipment.

The instructions and safety information referred to in the first, second and third subparagraphs of this paragraph shall be in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

The Commission is empowered to adopt delegated acts in accordance with Article 44 in order to amend Parts II and IV of Annex Ia, as a consequence of amendments to Part I of that Annex, or as a consequence of future amendments to labelling requirements, or in the light of technological progress, by introducing, modifying, adding or removing any details in relation to the information, graphic or textual elements, as set out in this Article.';

In the case of radio equipment intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, the safety information in paper format. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

(a) mark on the radio equipment, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the radio equipment; this requirement also applies where the instructions are embedded in the software of the radio equipment;

(c) make them accessible online during the expected lifetime of the radio equipment and for at least 10 years after the placing on the market of the radio equipment.

However, the end-user may, at time of the purchase of the radio equipment, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.';

(e) paragraph 9 is amended as follows:

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

'Manufacturers shall ensure that each item of radio equipment is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed.';

(ii) the second sentence is deleted;

(f) in paragraph 12, the first sentence is replaced by the following:

'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the radio equipment with this Directive, in a language which can be easily understood by that authority.';

(3) in Article 11(2), point (b), is replaced by the following:

'(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of radio equipment;';

(4) Article 12 is amended as follows:

(a) in paragraph 3, the first and second sentences are replaced by the following:

'Importers shall indicate on the radio equipment their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the radio equipment. This includes cases where the size of radio equipment does not allow it, or where importers would have to open the packaging in order to indicate their name, postal address and digital contact on the radio equipment.';

(b) in paragraph 9, the first sentence is replaced by the following:

'Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of radio equipment in a language which can be easily understood by that authority.';

(5) in Article 13(5), the first sentence is replaced by the following:

'Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of radio equipment.';

(6) the following Article 16a is inserted:

'Article 16a

Common Specifications

1. The Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set out in Article 3 in any of the following cases:

(a) requirements set out in Article 3 are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*;

(b) requirements set out in Article 3 are covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, but application of those standards or parts thereof results in non-compliance of radio equipment with the essential requirements set out in Article 3; or

(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant radio equipment.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 45(2).

2. Radio equipment that is in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Article 3.';

(7) Article 17 is amended as follows:

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

'3. Where, in assessing the compliance of radio equipment with the essential requirements set out in Article 3(2) and (3), the manufacturer has applied harmonised standards the references of which have been published in the Official Journal of the European Union, or common specifications, the manufacturer shall use any of the following procedures:';

(b) In paragraph 4, the first sentence is replaced by the following:

'4. Where, in assessing the compliance of radio equipment with the essential requirements set out in Article 3(2) and (3), the manufacturer has not applied or has applied only in part harmonised standards the references of which have been published in the Official Journal of the European Union, or common specifications, or where such harmonised standards or common specifications do not exist, radio equipment shall be submitted with regard to those essential requirements to either of the following procedures:';

(c) the following paragraph 5 is added:

'5. Where applicable, manufacturers shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.';

(8) Article 18 is amended as follows:

(a) in paragraph 2, the second subparagraph is deleted;

(b) the following paragraph 5 is added:

'5. Where other Union legislation applicable to radio equipment requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex IV to be included in the EU declaration of conformity and the instructions referred to in Article 10(8) shall be provided only in that digital product passport.';

(9) in Article 26(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential requirements set out in Article 3, of the applicable harmonised standards, of the applicable common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;’;

(10) Annexes Ia, and III to, IV, V, VI and VII are amended in accordance with Annex XI to this Directive.

Article 12

Amendments to Directive 2014/68/EU

Directive 2014/68/EU is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (22a) is inserted:

‘(22a) ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;’;

(b) the following point (24a) is inserted:

‘(24a) ‘common specifications’ means a set of technical requirements, other than a standard, that provide means of complying with the essential requirements applicable to a product, device, service, process or system;’;

(2) Article 6 is amended as follows:

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

‘Where compliance of the pressure equipment or assemblies referred to in Article 4(1) and (2) with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph of this paragraph, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.’;

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

‘Changes in design or characteristics of pressure equipment or assemblies and changes in the harmonised standards or in the common specifications or in other technical specifications by reference to which conformity of pressure equipment or assemblies is declared shall be adequately taken into account.’;

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the pressure equipment or assembly their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on the packaging or in a document accompanying the equipment or assembly. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’;

(d) paragraph 7 is replaced by the following:

‘7. Manufacturers shall ensure that the pressure equipment or assemblies referred to in Article 4(1) and (2) is accompanied by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and safety

information may be provided in electronic form. Such instructions and safety information shall be clear, understandable and intelligible.

Manufacturers shall ensure that the pressure equipment or assemblies referred to in Article 4(3) are accompanied by instructions and safety information in accordance with Article 4(3), in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and safety information may be provided in electronic form. Such instructions and safety information shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the pressure equipment or assemblies when deciding the specific format for the instructions and safety information.

In the case of pressure equipment or assemblies intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, the safety information in accordance with points 3.3 and 3.4 of Annex I. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

(a) mark on the pressure equipment or assemblies or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the pressure equipment or assemblies; this requirement also applies where the instructions are embedded in the software of the pressure equipment or assemblies;

(c) make them accessible online during the expected lifetime of the pressure equipment or assemblies and for at least 10 years after the placing on the market of the pressure equipment or assemblies.

However, the end-user may, at time of the purchase of the pressure equipment or assemblies, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.';

(e) paragraph 9 is amended as follows:

(a) the first sentence is replaced by the following:

'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the pressure equipment or assembly with this Directive, in a language which can be easily understood by that authority.';

(b) the second sentence is deleted;

(3) in Article 7(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the pressure equipment or assembly;’;

(4) Article 8 is amended as follows:

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

‘Importers shall indicate their name, registered trade name or registered trademark as well as their postal address and digital contact on the pressure equipment or assembly, or, where that is not possible, on its packaging or in a document accompanying the equipment or assembly.’;

(b) paragraph 9 is amended as follows:

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

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of pressure equipment or an assembly in a language which can be easily understood by that authority.’;

(ii) the second sentence is deleted;

(5) Article 9 is amended as follows:

(a) the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of pressure equipment or assemblies.’;

(b) the second sentence is deleted;

(6) the following Article 12a is inserted:

‘Article 12a

Common Specifications

1. The Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set out in Annex I in any of the following cases:

(a) requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*;

(b) requirements set out in Annex I are covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, but application of those standards or parts thereof results in non-compliance of pressure equipment or assemblies referred to in Article 4(1) and (2) with the essential requirements set out in Annex I; or

(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant pressure equipment or assemblies.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 44(2).

2. Pressure equipment or assemblies that are in conformity with the common specification shall be presumed to be in conformity with essential requirements covered by those common specifications or parts thereof, set out in Annex I.';

(7) Article 14 is amended as follows:

(a) paragraph 8 is replaced by the following:

'8. The records and correspondence relating to conformity assessment procedures shall be drafted, in electronic form, in an official language of the Member State where the body responsible for carrying out these conformity assessment procedures is established, or in a language accepted by that body.';

(b) the following paragraph 9 is added:

'9. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.';

(8) in Article 15(5), the first sentence is replaced by the following:

'The notified body which issued the European approval for materials shall withdraw that approval if it finds that it should not have been issued or if the type of materials is covered by a harmonised standard or common specifications.';

(9) in Article 17, the following paragraph 5 is added:

'5. Where other Union legislation applicable to the pressure equipment or assembly requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex IV to be included in the EU declaration of conformity and the instructions referred to in Article 6(7) shall be provided only in that digital product passport.';

(10) in Article 24(7), point (c) is replaced by the following:

'(c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;';

(11) in Article 25(7), point (c) is replaced by the following:

'(c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;';

(12) in Article 34, paragraph 3 is replaced by the following:

'3. Where a conformity assessment body finds that essential safety requirements set out in Annex I or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.';

(13) Annexes I, III and IV are amended in accordance with Annex XII to this Directive.

Article 13

Amendments to Directive 2014/90/EU

Directive 2014/90/EU is amended as follows:

(1) in Article 2, the following point (14a) is inserted:

‘(14a) ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;’;

(2) Article 12 is amended as follows:

(a) paragraph 3 is replaced by the following:

‘3. Where the compliance of marine equipment with the applicable requirements has been demonstrated by the conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, in accordance with Article 16, and affix the wheel mark in accordance with Articles 9 and 10.’;

(b) paragraphs 7 and 8 are replaced by the following:

‘7. Manufacturers shall indicate their name, registered trade name or registered trademark as well as their postal address and digital contact on the product or, where that is not possible, on its packaging or in a document accompanying the product or both, as appropriate. The postal address and digital contact must indicate a single point through which the manufacturer can be reached.

8. Manufacturers shall ensure that the product is accompanied by instructions and all necessary information for safe installation on board and safe use of the product, including limitations of use, if any, that can be easily understood by the end-users, together with any other documentation required by the international instruments or testing standards. The instructions and all the necessary information may be provided in electronic form.

In the case of products intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the product, information for safe installation on board and safe use of the product, including limitations of use. Such safety information shall be easily visible and legible for consumers.

When the instructions, referred to in the first subparagraph, are provided in electronic form, manufacturers shall:

(a) mark on the product, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the product; this requirement also applies where the instructions are embedded in the software of the product;

(c) make them accessible online during the expected lifetime of the product and for at least 10 years after the placing on the market of the product.

However, the end-user may, at time of the purchase of the product, or up to six months after that purchase, request the instructions or information for safe installation on board and safe use of the product, including limitations of use in paper format. Where the end-user requests those instructions or information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.’;

(c) in paragraph 10, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent authority, promptly provide it, in electronic form, with all the information and documentation necessary to

demonstrate the conformity of the product, in a language which can be easily understood by or is acceptable to that authority, grant that authority access to their premises for market surveillance purposes in accordance with Article 19 of Regulation (EC) No 765/2008 and provide samples or access to samples in accordance with Article 25(4) of this Directive.';

(3) Article 13 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. A manufacturer who is not located in the territory of at least one Member State shall, by a written mandate, appoint an authorised representative for the Union and shall indicate in the mandate the name of the authorised representative and the postal address and digital contact through which it can be reached.';

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

'(b) further to a reasoned request from a competent authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product';

(4) Article 14 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Importers shall indicate their name, registered trade name or registered trademark as well as their postal address and digital contact on the product or, where that is not possible, on its packaging or in a document accompanying the product or both, as appropriate.';

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

'Importers and distributors shall, further to a reasoned request from a competent authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product in a language which can be easily understood by, or is acceptable to, that authority.';

(5) in Article 15, the following paragraph 4 is added:

'4. The manufacturer shall provide to the notified body carrying out the conformity assessment procedure all the information and documentation relating to conformity assessment procedures in electronic form.';

(6) Article 16 is amended as follows:

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

'When marine equipment is placed on board an EU ship the manufacturer shall upload the EU declaration of conformity covering the equipment concerned onto the database set up by the Commission in accordance with Article 35(4).';

(b) paragraph 5 is replaced by the following:

'5. The EU declaration of conformity shall be provided to the notified body or to the bodies which carried out the relevant conformity assessment procedures via the database set up by the Commission in accordance with Article 35(4).';

(7) the following paragraph 6 is added:

'6. Where other Union legislation applicable to the marine equipment requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required Annex III to Decision No

768/2008/EC to be included in the EU declaration of conformity and the instructions referred to in Article 12(8) shall be provided only in that digital product passport.';

(8) in Article 29(1), point (f) is replaced by the following:

'(f) the EU declaration of conformity has not been made accessible electronically to the ship;';

(9) Annex II is amended in accordance with Annex XIII to this Directive.

Article 14

Transitional provision

Member States shall not impede the making available on the market of products which were placed on the market in accordance with Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU before [*PO: Please insert the date set out in Article 15(1), second subparagraph*].

Article 15

Transposition

1. Member States shall adopt and publish, by [*OP:Please insert 12 months after entry into force of this amending Directive*] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

   They shall apply those provisions from [*OP: Please insert 12 months after entry into force of this amending Directive*].

   However, Member States shall apply the following provisions from [*OP: Please insert 24 months after entry into force of this amending Directive*]:

(a) Article 1;

(b) Article 2, point (1)(a), point (2)(a), (c) and(d), and points (3), (4), (5) and (6);

(c) Article 3, point (1)(a), point (2)(a), (c) and(d), and points (3), (4), (5), (7) and (8);

(d) Article 4, point (1)(a), point (2)(a), (c), (d) and(e), and points (3), (4) and (5), point (7)(b) and(c), and point (8);

(e) Article 5, point (1)(a), point (2)(a), (c), (d) and(e), and points (3), (4), (5), (7) and (8);

(f) Article 6, point (1)(a), point (2)(a), (c), (d) and (e), and points (3), (4), (5), (7) and (8);

(g) Article 7, point (1)(a), point (2)(a), (c), (d) and(e), and points (3), (4), (5), (7), (9) and (12);

(h) Article 8, point (1)(a), point (2), point (3)(a), (c), (d) and (e), and points (4) (5), (6), (8), (9), (10) and (13);

(i) Article 9, point (1)(a), point (2)(a), (c), (d) and (e), and points (3), (4), (5), (7), (8) and (11);

(j) Article 10, point (1)(a), point (2)(a), (c), (d) and (e), and points (3), (4), (5) and (7);

(k) Article 11, point (1)(a), point (2)(a), (c), (d), (e) and (f), and points (3), (4) and (5), point (7)(c) and point (8);

(l) Article 12, point (1)(a), point (2)(a), (c), (d) and(e), and points (3), (4), (5), (7) and (9);

(m) Article 13;

(n) Annexe I;

(o) Annex II, point (1) and point (2)(a);

(p) Annex III, point (1)(a)(ii) and (b)(i), point (2)(a), point (3)(a) and point (4);

(q) Annex IV, point (1)(a)(i) and(c), point (2) and point (3)(a);

(r) Annex V, point (2)(a)(i) and (b) and point 3(a);

(s) Annex VI, point (1)(a)(i),(c), (d) and(g) and point (2)(a);

(t) Annex VII, point (1)(b)(i), first indent, (b)(iii), (d)(i), (e)(i), (f)(i), (g)(i), (k)(i), (l)(i), (l)(iv), first indent, and (l)(v), and point (2)(a);

(u) Annex VIII, point (1)(a)(i), (a)(iii), (b)(i) and (b)(iii), point (2)(a)(i), (a)(v), (b)(i) and (b)(v), point (4)(a), point (5)(a), point (6)(a), point (7)(a), point (8)(a), point (9)(a) and point 10(a);

(v) Annex IX, point (1), point (2)(a), (d) and(a), point 5(a) and point 8(a);

(w) Annex X, point (2)(a);

(x) Annex XI, point (1), point (2)(a)(i) and (b), point (3)(a), point (5)(a) and point (6);

(y) Annex XII, point (2)(c)(i), first indent, (c)(iv), (c)(v), first indent, (c)(viii), (e)(i), (f)(ii), (g)(i), (h)(ii), (k)(i), (l)(i), (l)(v) and (l)(viii), and point (3)(a) and (c);

(z) Annex XIII.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 16

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 17

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

LEGISLATIVE FINANCIAL AND DIGITAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards the digitalisation and alignment of common specifications

1.2. Policy area(s) concerned

Better Regulation, Competitiveness

1.3. Objective(s)

1.3.1. General objective(s)

To support the growth and development of companies, thus increasing their competitiveness and contribution to European welfare and prosperity.

To promote a business environment and to reduce administrative burdens for companies, thereby enhancing their ability to innovate, create jobs, and contribute to economic growth.

1.3.2. Specific objective(s)

Removing paper format references for declaration of conformity for for manufactures who have to provide such declarations of conformity under New Legislative Framework ('NLF') directives and regulations,

Introducing possibility for the manufacturer to provide a digital format of the instructions for use,

To provide alternative options to give businesses legal certainty on compliance with the EU rules, in situations where harmonised standards do not exist, are not available or there is an urgent need.

1.3.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The proposal/initiative is expected to have the following effects on the beneficiaries/groups targeted:

- reduce burden of paper copies,

- Reduced administrative burdens: manufacturers will experience a reduction in administrative burdens, which will enable them to focus on their core business activities and improve their competitiveness

- Improved competitiveness: manufacturer will become more competitive, both domestically and internationally, which will enable them to increase their market share and contribute to European economic growth

- Job creation: The growth and development of manufacturers will lead to the creation of new jobs, which will contribute to reducing unemployment and promoting social cohesion

- Increased innovation: digitalisation of declarations of conformity, of instructions will encouraged innovation and create new incentives to invest in data collection and processing with eGovernment solutions, which will contribute to improving the overall innovation capacity of the European economy

Target groups:

The proposal/initiative is targeted at the approximately manufacturers active in the field of the abovementioned directives.

1.3.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

N/A

1.4. The proposal/initiative relates to: None of the below.

☐ a new action

☐ a new action following a pilot project / preparatory action[22]

☐ the extension of an existing action

☐ a merger or redirection of one or more actions towards another/a new action

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

This proposal concerns two omnibus acts amending EU legislation. It can therefore only be carried out at EU level.

1.5.2. Added value of EU involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this section 'added value of EU involvement' is the value resulting from EU action, that is additional to the value that would have been otherwise created by Member States alone.

N/A

1.5.3. Lessons learned from similar experiences in the past

N/A

1.5.4. Compatibility with the multiannual financial framework and possible synergies with other appropriate instruments

N/A

1.5.5. Assessment of the different available financing options, including scope for redeployment

N/A

[22] As referred to in Article 58(2), point (a) or (b) of the Financial Regulation.

1.6. Duration of the proposal/initiative and of its financial impact

☐ **limited duration**

– ☐ in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☐ **unlimited duration**

– Implementation with a start-up period from YYYY to YYYY,

– followed by full-scale operation.

1.7. Method(s) of budget implementation planned[23]

☐ **Direct management** by the Commission

– ☐ by its departments, including by its staff in the Union delegations;

– ☐ by the executive agencies

☐ **Shared management** with the Member States

☐ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated

– ☐ international organisations and their agencies (to be specified)

– ☐ the European Investment Bank and the European Investment Fund

– ☐ bodies referred to in Articles 70 and 71 of the Financial Regulation

– ☐ public law bodies

– ☐ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees

– ☐ bodies or persons entrusted with the implementation of specific actions in the common foreign and security policy pursuant to Title V of the Treaty on European Union, and identified in the relevant basic act

– ☐ bodies established in a Member State, governed by the private law of a Member State or Union law and eligible to be entrusted, in accordance with sector-specific rules, with the implementation of Union funds or budgetary guarantees, to the extent that such bodies are controlled by public law bodies or by bodies governed by private law with a public service mission, and are provided with adequate financial guarantees in the form of joint and several liability by the controlling bodies or equivalent financial guarantees and which may be, for each action, limited to the maximum amount of the Union support.

Comments

[23] Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: https://myintracomm.ec.europa.eu/corp/budget/financial-rules/budget-implementation/Pages/implementation-methods.aspx.

N/A

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

N/A

2.2. Management and control system(s)

2.2.1. Justification of the budget implementation method(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

N/A

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

N/A

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio between the control costs and the value of the related funds managed), and assessment of the expected levels of risk of error (at payment & at closure)

N/A

2.3. Measures to prevent fraud and irregularities

N/A

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[24]	from EFTA countries [25]	from candidate countries and potential candidates [26]	From other third countries	other assigned revenue
	N/A	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.	from EFTA countries	from candidate countries and potential candidates	from other third countries	other assigned revenue
	N/A	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO

[24] Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
[25] EFTA: European Free Trade Association.
[26] Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ☐ The proposal/initiative requires the use of operational appropriations, as explained below

3.2.1.1. Appropriations from voted budget

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	

DG: <…….>			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[27]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

DG: <…….>			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitments	(1a)					**0.000**

[27] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[28]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
TOTAL operational appropriations	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations under HEADING <….> of the multiannual financial framework	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

Heading of multiannual financial framework	Number	

DG: <…….>	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**

[28] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[29]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b +3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

DG: <…….>			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[30]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b +3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**

29 Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

30 Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

TOTAL operational appropriations	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations under HEADING <….> of the multiannual financial framework	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
• TOTAL operational appropriations (all operational headings)	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations Under Heading 1 to 6 of the multiannual financial framework (Reference amount)	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

Heading of multiannual financial framework	**7**	‘Administrative expenditure’[31]				
DG: <…….>		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**

[31] The necessary appropriations should be determined using the annual average cost figures available on the appropriate BUDGpedia webpage.

• Human resources		0.000	0.000	0.000	0.000	**0.000**
• Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <…….>	Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

DG: <…….>		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
• Human resources		0.000	0.000	0.000	0.000	**0.000**
• Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <…….>	Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

EUR million (to three decimal places)

		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
TOTAL appropriations under HEADINGS 1 to 7	Commitments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
of the multiannual financial framework	Payments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.1.2. Appropriations from external assigned revenues

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	

DG: <…….>	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**

Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[32]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

DG: <…….>	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**

Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[33]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
TOTAL operational appropriations	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**

[32] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

[33] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations under HEADING <….>	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
of the multiannual financial framework	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Heading of multiannual financial framework	Number						

DG: <…….>			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[34]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

DG: <…….>			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**

[34] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[35]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
TOTAL operational appropriations	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations under HEADING <….> of the multiannual financial framework	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

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			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
• TOTAL operational appropriations (all operational headings)	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)	0.000	0.000	0.000	0.000	**0.000**

[35] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

TOTAL appropriations under Headings 1 to 6 of the multiannual financial framework (Reference amount)	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

Heading of multiannual financial framework	**7**	'Administrative expenditure'[36]

EUR million (to three decimal places)

DG: <…….>		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
• Human resources		0.000	0.000	0.000	0.000	**0.000**
• Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <…….>	Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

DG: <…….>		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
• Human resources		0.000	0.000	0.000	0.000	**0.000**
• Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <…….>	Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

EUR million (to three decimal places)

	Year	Year	Year	Year	**TOTAL MFF**

[36] The necessary appropriations should be determined using the annual average cost figures available on the appropriate BUDGpedia webpage.

		2024	2025	2026	2027	2021-2027
TOTAL appropriations under HEADINGS 1 to 7	Commitments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
of the multiannual financial framework	Payments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.2. Estimated output funded from operational appropriations (not to be completed for decentralised agencies)

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇩			Year **2024**		Year **2025**		Year **2026**		Year **2027**		Enter as many years as necessary to show the duration of the impact (see Section1.6)						**TOTAL**	
	OUTPUTS																	
	Type[37]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1[38]…																		
- Output																		
- Output																		
- Output																		
Subtotal for specific objective No 1																		
SPECIFIC OBJECTIVE No 2 ...																		
- Output																		
Subtotal for specific objective No 2																		

37 Outputs are products and services to be supplied (e.g. number of student exchanges financed, number of km of roads built, etc.).

38 As described in Section 1.3.2. 'Specific objective(s)'

TOTALS																

3.2.3. Summary of estimated impact on administrative appropriations

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☐ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below

3.2.3.1. Appropriations from voted budget

VOTED APPROPRIATIONS	Year 2024	Year 2025	Year 2026	Year 2027	TOTAL 2021 - 2027
HEADING 7					
Human resources	0.000	0.000	0.000	0.000	**0.000**
Other administrative expenditure	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Outside HEADING 7					
Human resources	0.000	0.000	0.000	0.000	**0.000**
Other expenditure of an administrative nature	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

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3.2.3.2. Appropriations from external assigned revenues

EXTERNAL ASSIGNED REVENUES	Year 2024	Year 2025	Year 2026	Year 2027	TOTAL 2021 - 2027
HEADING 7					
Human resources	0.000	0.000	0.000	0.000	**0.000**
Other administrative expenditure	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Outside HEADING 7					
Human resources	0.000	0.000	0.000	0.000	**0.000**
Other expenditure of an administrative nature	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.3.3. Total appropriations

TOTAL VOTED APPROPRIATIONS + EXTERNAL ASSIGNED REVENUES	Year 2024	Year 2025	Year 2026	Year 2027	TOTAL 2021 - 2027
HEADING 7					
Human resources	0.000	0.000	0.000	0.000	**0.000**
Other administrative expenditure	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Outside HEADING 7					

Human resources	0.000	0.000	0.000	0.000	**0.000**
Other expenditure of an administrative nature	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

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The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together, if necessary, with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

3.2.4. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources

– ☐ The proposal/initiative requires the use of human resources, as explained below

3.2.4.1. Financed from voted budget

Estimate to be expressed in full-time equivalent units (FTEs)[39]

VOTED APPROPRIATIONS		Year **2024**	Year **2025**	Year **2026**	Year **2027**
• Establishment plan posts (officials and temporary staff)					
20 01 02 01 (Headquarters and Commission's Representation Offices)		0	0	0	0
20 01 02 03 (EU Delegations)		0	0	0	0
01 01 01 01 (Indirect research)		0	0	0	0
01 01 01 11 (Direct research)		0	0	0	0
Other budget lines (specify)		0	0	0	0
• External staff (inFTEs)					
20 02 01 (AC, END from the 'global envelope')		0	0	0	0
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0
Admin. Support line [XX.01.YY.YY]	- at Headquarters	0	0	0	0
	- in EU Delegations	0	0	0	0
01 01 01 02 (AC, END - Indirect research)		0	0	0	0
01 01 01 12 (AC, END - Direct research)		0	0	0	0
Other budget lines (specify) - Heading 7		0	0	0	0
Other budget lines (specify) - Outside Heading 7		0	0	0	0
TOTAL		**0**	**0**	**0**	**0**

3.2.4.2. Financed from external assigned revenues

EXTERNAL ASSIGNED REVENUES	Year	Year	Year	Year

[39] Please specify below the table how many FTEs within the number indicated are already assigned to the management of the action and/or can be redeployed within your DG and what are your net needs.

		2024	2025	2026	2027
• Establishment plan posts (officials and temporary staff)					
20 01 02 01 (Headquarters and Commission's Representation Offices)		0	0	0	0
20 01 02 03 (EU Delegations)		0	0	0	0
01 01 01 01 (Indirect research)		0	0	0	0
01 01 01 11 (Direct research)		0	0	0	0
Other budget lines (specify)		0	0	0	0
• External staff (in full time equivalent units)					
20 02 01 (AC, END from the 'global envelope')		0	0	0	0
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0
Admin. Support line [XX.01.YY.YY]	- at Headquarters	0	0	0	0
	- in EU Delegations	0	0	0	0
01 01 01 02 (AC, END - Indirect research)		0	0	0	0
01 01 01 12 (AC, END - Direct research)		0	0	0	0
Other budget lines (specify) - Heading 7		0	0	0	0
Other budget lines (specify) - Outside Heading 7		0	0	0	0
TOTAL		**0**	**0**	**0**	**0**

3.2.4.3. Total requirements of human resources

TOTAL VOTED APPROPRIATIONS + EXTERNAL ASSIGNED REVENUES		Year **2024**	Year **2025**	Year **2026**	Year **2027**
• Establishment plan posts (officials and temporary staff)					
20 01 02 01 (Headquarters and Commission's Representation Offices)		0	0	0	0
20 01 02 03 (EU Delegations)		0	0	0	0
01 01 01 01 (Indirect research)		0	0	0	0
01 01 01 11 (Direct research)		0	0	0	0
Other budget lines (specify)		0	0	0	0
• External staff (in full time equivalent units)					
20 02 01 (AC, END from the 'global envelope')		0	0	0	0
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0
Admin. Support line [XX.01.YY.YY]	- at Headquarters	0	0	0	0
	- in EU Delegations	0	0	0	0
01 01 01 02 (AC, END - Indirect research)		0	0	0	0
01 01 01 12 (AC, END - Direct research)		0	0	0	0
Other budget lines (specify) - Heading 7		0	0	0	0
Other budget lines (specify) - Outside Heading 7		0	0	0	0
TOTAL		**0**	**0**	**0**	**0**

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The staff required to implement the proposal (in FTEs):

	To be covered by current staff available in the	**Exceptional additional staff***

	Commission services			
		To be financed under Heading 7 or Research	**To be financed from BA line**	**To be financed from fees**
Establishment plan posts			N/A	
External staff (CA, SNEs, INT)				

Description of tasks to be carried out by:

Officials and temporary staff	
External staff	

3.2.5. Overview of estimated impact on digital technology-related investments

Compulsory: the best estimate of the digital technology-related investments entailed by the proposal/initiative should be included in the table below.

Exceptionally, when required for the implementation of the proposal/initiative, the appropriations under Heading 7 should be presented in the designated line.

The appropriations under Headings 1-6 should be reflected as "Policy IT expenditure on operational programmes". This expenditure refers to the operational budget to be used to re-use/ buy/ develop IT platforms/ tools directly linked to the implementation of the initiative and their associated investments (e.g. licences, studies, data storage etc). The information provided in this table should be consistent with details presented under Section 4 "Digital dimensions".

TOTAL Digital and IT appropriations	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021 - 2027**
HEADING 7					
IT expenditure (corporate)	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Outside HEADING 7					
Policy IT expenditure on operational programmes	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.6. Compatibility with the current multiannual financial framework

The proposal/initiative:

– ☐ can be fully financed through redeployment within the relevant heading of the multiannual financial framework (MFF)

N/A

– ☐ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation

N/A

– ☐ requires a revision of the MFF

N/A

3.2.7. Third-party contributions

The proposal/initiative:

– ☐ does not provide for co-financing by third parties

– ☐ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year **2024**	Year **2025**	Year **2026**	Year **2027**	Total
Specify the co-financing body					
TOTAL appropriations co-financed					

3.3. Estimated impact on revenue

– ☐ The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

– ☐ on own resources

– ☐ on other revenue

– ☐ please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[40]			
		Year **2024**	Year **2025**	Year **2026**	Year **2027**
Article …….					

For assigned revenue, specify the budget expenditure line(s) affected.

N/A

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

N/A

[40] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20% for collection costs.

4. DIGITAL DIMENSIONS

4.1. Requirements of digital relevance

Requirement 1:

- Reference: Article 1(1), Article 2 (1a, 1c) and other
- High-level descrittion: Definition of 'digital contact': any up-to-date and accessible online communication channel
- Stakeholders: Economic Operators, Consumers and other End-users, Member States Authorities.
- High-level processes: Market surveillance verification and monitoring.

Requirement 2:

- Reference: Article 1 (2)(3)(4)(5) and other
- High-level description: the products must be accompanied by the internet address or machine-readable code through which the EC declaration of conformity can be accessed.
- Stakeholders: Economic Operators, Member States Authorities.
- High-level processes: Market surveillance verification and monitoring.

Requirement 3:

- Reference: Article 1(6)(a), Article 2(2a) and other
- High-level description: Definition of EC declaration of conformity, in electronic form.
- Stakeholders: Economic Operators, Member States Authorities.
- High-level processes: Market surveillance verification and monitoring.

Requirement 4:

- Reference: Article 1(6)(b) and other
- High-level description: include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EC declaration of conformity or instructions in a digital product passport.
- Stakeholders: Economic Operators, Member States Authorities.
- High-level processes: Market surveillance verification and monitoring

Requirement 5:

- Reference: Article 1 (7)(a) and other
- High-level description: Member States shall ensure that the Commission and any other Member State may, on a reasoned request, obtain all information, in electronic form.
- Stakeholders: Economic Operators, Member States Authorities, European Commission.
- High-level processes: conformity assessment procedure

Requirement 6:

- Reference: Article 1(7b) and other
- High-level description: Where appropriate, the manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.

- Stakeholders: Notified Bodies, Economic Operators
- High-level processes: Conformity assessment procedures

Requirement 7:

- Reference: Article 2 (1b) and other
- High-level description: 'a common specification' can be digital or structured in a manner that can facilitate interoperability.
- Stakeholders: European Commission, Economic Operators, Notified Bodies, Market Surveillance Authorities.
- High-level processes: Conformity assessment procedures, Market surveillance verification and monitoring.

Requirement 8:

- Reference: Article 3(2) and other
- High-level description: The instructions and safety information may be provided in electronic form. It could be further specified that the format should comply with the accessibility requirements.
- Stakeholders: Economic Operators, Consumers and other End-users, Market surveillance authorities
- High-level processes: Market surveillance verification and monitoring, Conformity assessment.

4.2. Data

The definition "electronic form" allows plain text files, PDF files, Microsoft Word Documents, Web pages. While this is an improvement compared to the paper format, interoperability can be further improved by using a format which allows interconnection of IT systems.

4.3. Digital solutions

N/A

4.4. Interoperability assessment

Digital public service: Market surveillance monitoring/verification/investigations. Certification services.

Legal layer interoperability: Further interoperability can be achieved with the revision of the NLF.

Semantic layer potential barrier: The structure of the digital contact, EU declaration of conformity and common specifications could be better defined.

Technical interoperability potential barrier: The "electronic form" definition can hinder interoperability because it is possible to use formats which are not interoperable, like websites, unstructured word documents and PDF files, even videos or photos.

4.5. Measures to support digital implementation

The revision of the NLF and the Digital Product Passport Implementing Acts will take into consideration all digital requirements for further interoperability in all processes in scope of this directive. Particular attention will be paid to the cybersecurity aspects.

The Commission will ensure that the common specifications are defined in the implementing acts in a structured manner, to allow interoperability. The verification and certification processes could be further defined to allow automatisation and require measures to address cybersecurity possible threats.

EUROPEAN
COMMISSION

Brussels, 21.5.2025
COM(2025) 503 final

ANNEXES 1 to 13

ANNEXES

to the

Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications

{SWD(2025) 130 final}

ANNEX I

Annexes II and V to VIII to Directive 2000/14/EC are amended as follows:

(1) Annex II is amended as follows:

(a) the first and second indents are replaced by the following:

‘— name, postal address and digital contact of the manufacturer or his authorised representative established in the Community

— name, postal address and digital contact of the person who keeps the technical documentation’;

(b) the fourth indent is replaced by the following:

‘— conformity assessment procedure followed, and, where appropriate, name, postal address and digital contact of the notified body involved’;

(2) Annex V is amended as follows:

(a) in point 2, the third sentence is replaced by the following:

‘In this case he has to include the name, postal address and digital contact of this person in the EC declaration of conformity.’;

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

‘— name, postal address and digital contact of the manufacturer or his authorised representative established in the Community’;

(3) Annex VI is amended as follows:

(a) in point 2, the third sentence is replaced by the following:

‘In this case he has to include the name, postal address and digital contact of this person in the EC declaration of conformity.’;

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

‘— name, postal address and digital contact of the manufacturer or his authorised representative established in the Community’;

(4) in Annex VII, point 2, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact in addition’;

(5) in Annex VIII, point 3.1, first indent, the first subindent is replaced by the following:

‘— name, postal address and digital contact of the manufacturer or his authorised representative established in the Community’.

ANNEX II

Annexes V and VI to Directive 2011/65/EU are amended as follows:

(1) in Annex V, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the applicant;’;

(2) Annex VI is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer or his authorised representative’;

(b) point 6 is replaced by the following:

‘6. Where applicable, references to the relevant harmonised standards or common specifications used or references to the technical specifications in relation to which conformity is declared:’.

ANNEX III

Annexes I, III, IV and V to Directive 2013/53/EU are amended as follows:

(1) Annex I is amended as follows:

(a) Part A is amended as follows:

(i) in point 2.1., the second subparagraph is replaced by the following:

‘Detailed requirements for the identification number referred to in the first paragraph are set out in the relevant harmonised standard or common specification.’;

(ii) in point 2.2, point (a) is replaced by the following:

‘(a) manufacturer’s name, registered trade name or registered trade mark and as well as the postal address and digital contact;’;

(b) Part B is amended as follows

(i) in point 1.1, point (a) is replaced by the following:

‘(a) engine manufacturer’s name, registered trade name or registered trade mark as well as the postal address and digital contact; and, if applicable, the name, postal address and digital contact of the person adapting the engine;’;

(ii) in point 2.3, the fourth subparagraph is replaced by the following:

‘Notified bodies may accept tests carried out on the basis of other tests cycles as specified in a harmonised standard or common specification and as applicable for the engine duty cycle.’;

(iii) in point 2.5, the second subparagraph is replaced by the following:

‘Notified bodies may accept tests carried out on the basis of other tests fuel as specified in a harmonised standard or common specification.’;

(iv) in point 4, point (b) is replaced by the following:

‘(b) specify the power of the engine when measured in accordance with the harmonised standard or common specification.’;

(2) Annex III is amended as follows:

(a) points (a), and (b) are replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer;

(b) the name, postal address and digital contact of the representative of the manufacturer established in the Union or, if appropriate, of the person responsible for the placing on the market;’;

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

‘(d) a statement that the partly completed watercraft complies with the essential requirements that apply at this stage of construction; this shall include references to the relevant harmonised standards or common specifications used, or references to the specifications in relation to which compliance is declared at this stage of construction; furthermore, it is intended to be completed by other legal or natural persons in full compliance with this Directive.’;

(3) Annex IV is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer or his authorised representative [The authorised representative must also give the business name, postal address and digital contact of the manufacturer] or the private importer.’;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:’;

(4) Annex V is amended as follows:

(a) in point 2, the first subparagraph is replaced by the following:

‘The person who is placing the product on the market or putting it into service shall lodge an application for a post-construction assessment of the product with a notified body and must provide the notified body, in electronic form, with the documents and technical file enabling the notified body to assess the conformity of the product with the requirements of this Directive and any available information on the use of the product after its first putting into service.’;

(b) in point 4.2, first subparagraph, the first sentence is replaced by the following:

‘The person who is placing the product on the market or putting it into service shall draw up, in electronic form, an EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the date the post-construction assessment certificate has been issued.’.

ANNEX IV

Annexes II, III and IV to Directive 2014/29/EU are amended as follows:

(1) Annex II is amended as follows:

(a) point 1.3 is amended as follows: :

(i) point (a) is replaced by the following

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(ii) in point (c), point (iv) is replaced by the following:

‘(iv) a list of the harmonised standards applied in full or in part, the references of which have been published in the *Official Journal of the European Union*, or common specifications, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(iii) in point (e), the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’;

(b) points 1.4.2., 1.4.3 and 1.4.4. are replaced by the following:

‘1.4.2. verify that the prototype vessel(s) has/have been manufactured in conformity with the technical documentation, that it may safely be used under its intended working conditions and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

1.4.3 carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;

1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of this Directive;’;

(c) in point 1.6, first paragraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(d) in point 3.3., first subparagraph, the second sentence is replaced by the following:

‘An adequate sample of the final vessels, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to check the conformity of the

vessel with the type described in the EU-type examination certificate and with the relevant requirements of this Directive.';

(2) in Annex III, point 1.2, point (e) is replaced by the following:

'(e) the name, registered trade name or registered trade mark as well as the postal address and digital contact of the manufacturer;';

(3) Annex IV is amended as follows

(a) point 2 is replaced by the following:

'2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative:';

(b) point 6 is replaced by the following:

'6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:'.

ANNEX V

Annexes II, III and IV to Directive 2014/30/EU are amended as follows:

(1) in Annex II, point 3, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(2) Annex III, Part A is amended as follows:

(a) point 3 is amended as follows:

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

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(ii) in point (c), point (iv) is replaced by the following:

‘(iv) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, or common specifications, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(b) in point 6, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(3) Annex IV is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer or his authorised representative:’;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used, including the date of the standard or common specification, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:’.

ANNEX VI

Annexes II and IV to Directive 2014/31/EU are amended as follows:

(1) Annex II is amended as follows:

(a) point 1.3 is amended as follows:

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

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(ii) in point (c), point (iv) is replaced by the following:

‘(iv) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(iii) in point (e), the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’;

(b) point 1.4.2, 1.4.3 and 1.4.4. are replaced by the following:

‘1.4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;

1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Directive;’;

(c) in point 1.6, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(d) in point 2.3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(e) in point 2.3.3., the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(f) in point 3.2., point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, or common specifications, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(g) in point 3.5.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(h) in point 3.5.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(i) point 4.4.1. is replaced by the following:

‘4.4.1. All instruments shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or in the relevant common specifications and/or other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’;

(j) in point 5.2.1., point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(k) point 5.5.1. is replaced by the following:

‘5.5.1. All instruments shall be individually examined and appropriate tests, set out in the relevant harmonised standards and/or equivalent tests set out in the relevant common specifications or other relevant technical specifications, shall be carried out to verify conformity with the requirements that apply to them. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.’;

(l) in point 6.2.1, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, or common specifications, and,

where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;';

(m) in point 6.4., the first subparagraph is replaced by the following:

'A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or in the relevant common specifications and/or other relevant technical specifications, to check the conformity of the instrument with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.';

(2) Annex IV is amended as follows:

(a) point 2 is replaced by the following:

'2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative';

(b) point 6 is replaced by the following:

'6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:'.

ANNEX VII

Annexes II and XIII to Directive 2014/32/EU are amended as follows:

(1) Annex II is amended as follows:

(a) in Module A2: INTERNAL PRODUCTION CONTROL PLUS SUPERVISED INSTRUMENT CHECKS AT RANDOM INTERVALS, point 4, first subparagraph, the second and third sentences are replaced by the following:

‘An adequate sample of the final measuring instruments, taken on site by the body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standard, and/or normative document, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify the conformity of the instruments with the relevant requirements of this Directive. In the absence of a relevant harmonised standard or normative document or common specification, the accredited in-house body or notified body concerned shall decide on the appropriate tests to be carried out.’;

(b) Module B: EU-TYPE EXAMINATION is amended as follows:

(i) point 3 is amended as follows

– point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

– point (e) is replaced by the following

‘(e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards, and/or common specifications, and/or normative documents have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.’;

(ii) in point 4, points 4.2, 4.3 and 4.4 are replaced by the following:

‘4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or normative documents, and/or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, normative documents, and common specifications, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards, and/or normative documents, and/or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Directive;’;

(iii) in point 6, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(c) in Module C2: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED INSTRUMENT CHECKS AT RANDOM INTERVALS, point 3, first subparagraph, the second sentence is replaced by the following:

‘An adequate sample of the final measuring instrument, taken on site by the accredited in-house body or by the notified body before the placing on the market, shall be examined and appropriate tests, as identified by the relevant parts of the harmonised standards, and/or normative documents, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify the conformity of the instrument with the type described in the EU-type examination certificate and with the relevant requirements of this Directive.’;

(d) Module D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS is amended as follows:

(i) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(ii) in point 3.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(e) Module D1: QUALITY ASSURANCE OF THE PRODUCTION PROCESS, is amended as follows:

(i) in point 5.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(ii) in point 5.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(f) Module E: CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE is amended as follows:

(i) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well’;

(ii) in point 3.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(g) Module E1: QUALITY ASSURANCE OF FINAL INSTRUMENT INSPECTION AND TESTING is amended as follows:

(i) in point 5.1, point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well';

(ii) in point 5.3, the second subparagraph is replaced by the following:

'It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.';

(h) Module F: CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION, is amended as follows:

(i) in point 4, point 4.1 is replaced by the following:

'4.1. All measuring instruments shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or normative documents, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of a harmonised standard or normative document or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.';

(ii) in point 5, point 5.2 is replaced by the following:

'5.2. A random sample shall be taken from each lot according to the requirements of point 5.3. All measuring instruments in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or normative document(s), and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the type described in the EU-type examination certificate and with the applicable requirements of this Directive, and to determine whether the lot is accepted or rejected. In the absence of such harmonised standard or normative document or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.';

(i) Module F1: CONFORMITY BASED ON PRODUCT VERIFICATION, is amended as follows:

(i) In point 5, point 5.1 is replaced by the following:

'5.1. All measuring instruments shall be individually examined and appropriate tests, set out in the relevant harmonised standards and/or normative documents, and/or common specifications and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify their conformity with the requirements that apply to them. In the absence of such a harmonised standard, or normative document, or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.';

(ii) in point 6, point 6.3 is replaced by the following:

'6.3. All measuring instruments in the sample shall be individually examined and appropriate tests set out in the relevant harmonised standards and/or normative documents, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the applicable requirements of this Directive and to determine whether the lot is accepted or rejected. In the absence of such harmonised standard, or normative document, or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.';

(j) in Module G: CONFORMITY BASED ON UNIT VERIFICATION, point 4, the first subparagraph is replaced by the following:

‘A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests set out in the relevant harmonised standards, and/or normative documents, and/or common specifications or equivalent tests set out in other relevant technical specifications, to verify the conformity of the instrument with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard, or normative document, or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’;

(k) Module H: CONFORMITY BASED ON FULL QUALITY ASSURANCE, is amended as follows:

(i) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well’;

(ii) in point 3.2, point (b) is replaced by the following:

‘(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards, and/or normative documents, and/or common specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the measuring instruments will be met applying other relevant technical specifications;’;

(iii) in point 3.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(l) Module H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION is amended as follows:

(i) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well’;

(ii) in point 3.2., point (b) is replaced by the following:

‘(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents, and/or common specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the measuring instruments will be met, applying other relevant technical specifications;’;

(iii) in point 3.3, first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(iv) point 4.2 is amended as follows:

– point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer’;

– point (d) is replaced by the following:

‘(d) the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or normative documents, and/or common specifications have not been applied in full, and shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications, by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.’;

(v) in point 4.3, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall give the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design.’;

(2) Annex XIII is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative’;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or normative documents or common specifications used or references to the other technical specifications in relation to which conformity is declared:’.

ANNEX VIII

Annexes IIand VI to XII to Directive 2014/33/EU are amended as follows:

(1) Annex II is amended as follows:

(a) Part A is amended as follows:

(i) points (a) and (b) are replaced by the following:

‘(a) business name, postal address and digital contact of the manufacturer;

(b) where appropriate, business name, postal address and digital contact of the authorised representative;’;

(ii) point (h) are replaced by the following:

‘(h) where appropriate, reference(s) to harmonised standard(s) or common specification(s) used;’;

(iii) points (i) to (k) are replaced by the following:

‘(i) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the EU-type examination of safety components for lifts set out in Annex IV, Part A and Annex VI, and the reference of the EU-type examination certificate issued by that notified body;

(j) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the conformity to type with random checking for safety components for lifts set out in Annex IX;

(k) where appropriate, the name, postal address, digital contact and identification number of the notified body which approved the quality system operated by the manufacturer in accordance with the conformity assessment procedure set out in Annex VI or VII;’;

(b) Part B is amended as follows:

(i) points (a) and (b) are replaced by the following:

‘(a) business name, postal address and digital contact of the installer;

(b) where appropriate, business name, postal address and digital contact of the authorised representative;’;

(ii) points (g) is replaced by the following:

‘(g) where appropriate, reference(s) to harmonised standard(s) or common specifications used;’;

(iii) points (h) to (k) are replaced by the following:

(h) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the EU-type examination of lifts set out in Annex IV, Part B and the reference of the EU-type examination certificate issued by that notified body;

(i) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the unit verification for lifts set out in Annex VIII;

(j) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the final inspection for lifts set out in Annex V;

(k) where appropriate, the name, postal address, digital contact and identification number of the notified body which approved the quality assurance system operated by the installer in accordance with the conformity assessment procedure set out in Annex X, XI or XII;’;

(2) Annex IV is amended as follows:

(a) Part A is amended as follows:

(i) in point 2, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well and the place of manufacture of the safety components for lifts;’;

(ii) in point 2(e), the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents, including other relevant technical specifications, that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’;

(iii) in point 3, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to enable the safety component for lifts to meet the conditions referred to in point 1, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(iv) in point 4, points (c), (d) and (e) are replaced by the following:

‘(c) verify that the representative specimen(s) has(have) been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

(d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the specifications of the relevant harmonised standards or common specifications, these have been applied correctly;

(e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the specifications of the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications enable the safety component for lifts to meet the conditions referred to in point 1.’;

(v) in point 5, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the EU-type examination, any conditions of validity of the certificate and the particulars necessary to identify the approved type.’;

(b) Part B is amended as follows:

(i) in point 2, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the installer; and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(ii) in point 2(e), the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents, including other relevant technical specifications that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’;

(iii) in point 3, point (e) is replaced by the following:

‘(e) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of the Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(iv) in point 4, points (c), (d) and (e) are replaced by the following:

‘(c) examine the specimen lift to check that it has been manufactured in accordance with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

(d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the installer has chosen to apply the specifications of the relevant harmonised standards or common specifications, these have been applied correctly;

(e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the specifications of the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the installer applying other relevant technical specifications meet the corresponding essential health and safety requirements of this Directive.’;

(v) in point 6, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the installer, the conclusions of the EU-type examination, any conditions of validity of the certificate and the particulars necessary to identify the approved type.’;

(3) Annex V is amended as follows:

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

‘(b) a lift designed and manufactured in accordance with a quality system pursuant to Annex XI and the EU design examination certificate if the design is not wholly in accordance with the harmonised standards or common specifications.’;

(b) in point 3.1, the third subparagraph is replaced by the following:

‘The appropriate examinations and tests set out in the relevant harmonised standard(s) or common specifications, or equivalent tests shall be carried out in order to check the conformity of the lift with the applicable essential health and safety requirements set out in Annex I.’;

(c) in point 3.2, point (b) is replaced by the following:

‘(b) examination of the documents referred to in point 3.1 to check that the lift conforms with the lift designed and manufactured in accordance with an approved quality system pursuant to

Annex XI and if the design is not wholly in accordance with the harmonised standards or common specifications, with the EU design examination certificate.';

(4) Annex VI, is amended as follows:

(a) point 3.1, point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';

(b) in point 3.2., first subparagraph, the first sentence is replaced by the following:

'Under the quality system, each safety component for lifts shall be inspected and appropriate tests as set out in the relevant harmonised standards or common specifications, or equivalent tests shall be carried out in order to ensure that it meets the conditions referred to in point 1.';

(c) in point 3.3., first subparagraph, the second sentence is replaced by the following:

'It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard or common specifications.';

(5) Annex VII is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';

(b) in point 3.2, point (b) is replaced by the following:

'(b) the technical design specifications, including standards that will be applied and, where the relevant harmonised standards or common specifications will not be applied or not applied in full, the means, including other relevant technical specifications, that will be used to ensure that the conditions referred to in point 1 will be met;';

(c) in point 3.3, first subparagraph, the second sentence is replaced by the following:

'It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard or common specifications.';

(6) Annex VIII is amended as follows:

(a) in point 2.2, point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the installer, and if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';

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

'(e) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of the Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;';

(c) in point 4, first subparagraph, the first sentence is replaced by the following:

‘The notified body chosen by the installer shall examine the technical documentation and the lift and carry out the appropriate tests as set out in the relevant harmonised standard(s) or common specification(s), or equivalent tests, to check its conformity with the applicable essential health and safety requirements set out in Annex I.’;

(7) Annex IX is amended as follows:

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

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

(b) in point 4, first subparagraph, the second sentence is replaced by the following:

‘An adequate sample of the final safety components for lifts, taken on site by the notified body, shall be examined and appropriate tests set out in the relevant harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to check whether the safety components for lifts meets the conditions referred to in point 1.’;

(8) Annex X is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the installer, and if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(b) in point 3.2, the first subparagraph is replaced by the following:

‘Under the quality system, each lift shall be examined and appropriate tests as set out in the relevant harmonised standards or common specifications, or equivalent tests shall be carried out in order to ensure its conformity with the applicable essential health and safety requirements set out in Annex I.’;

(c) in point 3.3, first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard or common specifications.’;

(9) Annex XI is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the installer, and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(b) in point 3.2, point (b) is replaced by the following:

‘(b) the technical design specifications, including standards that will be applied and, where the relevant harmonised standards or common specifications will not be applied in full, the means, including other relevant technical specifications that will be used to ensure that the applicable essential health and safety requirements set out in Annex I will be met;’;

(c) in point 3.3, point 3.3.1 is replaced by the following:

‘3.3.1. When the design is not entirely in accordance with harmonised standards or common specifications, the notified body shall ascertain whether the design conforms to the essential health and safety requirements set out in Annex I and, if it does, issue an EU design

examination certificate to the installer, stating the limits of the certificate's validity and giving the details required for identification of the approved design.';

(d) in point 3.4, first subparagraph, the second sentence is replaced by the following:

'It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard or common specifications.';

(10) Annex XII is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the installer, and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;'

(b) in point 3.3, first subparagraph, the second sentence is replaced by the following:

'It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.'.

ANNEX IX

Annexes II to V and VII to X to Directive 2014/34/EU are amended as follows:

(1) in Annex II, point 1.0.5, the first indent is replaced by the following:

‘— name, registered trade name or registered trade mark as well as postal address and digital contact of the manufacturer,’;

(2) Annex III is amended as follows:

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

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’ ;

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

‘(iv) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union,* or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’

(c) in point 4, points 4.1, 4.2, and 4.3 are replaced by the following:

‘4.1. examine the technical documentation, verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.2. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential health and safety requirements of this Directive;’;

(d) in point 6, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(3) Annex IV is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(b) in point 3.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(4) in Annex V, point 4, point 4.1 is replaced by the following:

‘4.1. All products shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or common specification(s) and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’;

(5) Annex VII is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(b) in point 3.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(6) in Annex VIII, point 2, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(7) Annex IX is amended as follows:

(a) in point 2.1, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

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

‘A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the product with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.’;

(8) Annex X is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative:’;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:’.

ANNEX X

Annexes III and IV to Directive 2014/35/EU are amended as follows:

(1) in Annex III, point 2, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* or international or national standards referred to in Articles 13 and 14 or common specifications referred to in Article 12a and, where those harmonised standards or international or national standards or common specifications have not been applied, descriptions of the solutions adopted to meet the safety objectives of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or international or national standards referred to in Articles 13 and 14 or common specifications, the technical documentation shall specify the parts which have been applied;’;

(2) Annex IV is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer or his authorised representative:’;

(b) point 6 is replaced by the following:

6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:’.

ANNEX XI

Annexes Ia, and III to VII to Directive 2014/53/EU are amended as follows:

(1) in Annex Ia, Part II, the introductory sentence is replaced by the following:

‘In the case of radio equipment falling within the scope of Article 3(4), first subparagraph, the following information shall be indicated in accordance with the requirements set out in Article 10(8):’;

(2) Annex III, Module B: EU-type examination, is amended as follows:

(a) point 3 is amended as follows:

(i) point (a) and (d) are replaced by the following:

‘(a) the name**,** postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;

(ii) in point (d), the second sentence is replaced by the following:

‘That supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied or have not been fully applied. ’;

(b) in point 6, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the assessed type.’;

(c) in point 8, third subparagraph, the first sentence is replaced by the following:

‘Each notified body shall inform the Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards the references of which have been published in the Official Journal of the European Union or common specifications have not been applied or not been fully applied.’;

(3) Annex IV is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(b) in point 3.2, point (b) is replaced by the following:

‘(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or common specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the radio equipment will be met;’;

(c) in point 3.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(4) in Annex V, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, or common specifications and,

where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Article 3, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;';

(5) Annex VI is amended as follows:

(a) point 2 is replaced by the following:

'2. Name, postal address and digital contact of the manufacturer or his authorised representative:';

(b) in point 6, the first sentence is replaced by the following:

'References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared.';

(6) Annex VII is deleted.

ANNEX XII

Annexes I, III and IV to Directive 2014/68/EU are amended as follows:

(1) Annex I is amended as follows:

(a) in point 3.1.2, the fifth subparagraph is replaced by the following:

‘To carry out these approvals the third party must perform examinations and tests as set out in the appropriate harmonised standards or common specifications or equivalent examinations and tests or shall have them performed.’;

(b) in point 4.2., point (b), the first indent is replaced by the following:

‘— by using materials which comply with harmonised standards or common specifications,’;

(c) in point 7, first subparagraph, the second sentence is replaced by the following:

‘However, where they are not applied, including in cases where materials are not specifically referred to and no harmonised standards or common specifications are applied, the manufacturer shall demonstrate that appropriate measures have been taken to achieve an equivalent overall level of safety.’;

(2) Annex III is amended as follows:

(a) in Part 1: Module A: (INTERNAL PRODUCTION CONTROL), point 2, the fourth indent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and a description of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(b) in Part 2: Module A2: INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS, point 2, the fourth indent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(c) Part 3: Module B: EU-TYPE EXAMINATION is amended as follows:

(i) in point 3.1 EU-Type examination – production type, point 3 is amended as follows:

– in the second subparagraph, the first indent is replaced by the following:

‘-the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

– in the second subparagraph, third indent, fourth subindent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

– in the fourth subparagraph, only indent, the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’;

(ii) in point 4.1, second subparagraph, the first indent is replaced by the following:

‘— assess the materials where these are not in conformity with the relevant harmonised standards or common specifications or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with point 4.3 of Annex I,’;

(iii) points 4.2., 4.3. and 4.4. are replaced by the following:

‘4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications as well as the elements which have been designed using other relevant technical specifications without applying the relevant provisions of those standards.

4.3. carry out appropriate examinations and necessary tests to check whether when the manufacturer has chosen to apply the solutions the relevant harmonised standards or common specifications, these have been applied correctly.

4.4. carry out appropriate examinations and necessary tests to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of this Directive.’;

(iv) in point 6, first subparagraph, the second sentence is replaced by the following:

‘Without prejudice to point 7, the certificate shall be valid for 10 years and be renewable and shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(v) in point 3.2. EU-Type examination – design type, point 3 is amended as follows:

– in the second subparagraph, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

– in the second subparagraph, third indent, the fourth subindent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

– in the second subparagraph, fourth indent, the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’;

(vi) in point 4.1., second subparagraph, the first indent is replaced by the following:

‘— assess the materials where these are not in conformity with the relevant harmonised standards or common specifications or with a European approval for pressure equipment materials,’;

(vii) points 4.2. and 4.3. are replaced by the following:

‘4.2. carry out appropriate examinations to check whether where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications these have been applied correctly.

4.3. carry out appropriate examinations to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential safety requirements of this Directive.’;

(viii) in point 6, first subparagraph, the second sentence is replaced by the following:

‘Without prejudice to point 7, the certificate shall be valid for 10 years and be renewable and shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved design.’;

(d) in Part 4: MODULE C2: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS, point 3, the third subparagraph is replaced by the following:

‘An adequate sample of the final pressure equipment, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or common specifications, and/or equivalent tests applying other technical specifications, shall be carried out to check the conformity of the pressure equipment with the relevant requirements of this Directive.’;

(e) Part 5: MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS is amended as follows:

(i) in point 3.1, second subparagraph, the first indent is replaced by the following:

‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(ii) in point 3.3., the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(f) Part 6: MODULE D1: QUALITY ASSURANCE OF THE PRODUCTION PROCESS is amended as follows:

(i) in point 2, first subparagraph, the fourth indent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(ii) in point 5.1, second subparagraph, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(iii) in point 5.3, first subparagraph, the second sentence is replaced by the following:

‘The elements of the quality system which conform to the relevant harmonised standard or common specification are presumed to comply with the corresponding requirements referred to in point 5.2.’;

(g) Part 7: MODULE E: CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT QUALITY ASSURANCE is amended as follows:

(i) in point 3.1, second subparagraph, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(ii) in point 3.3, first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(h) Part 8: MODULE E1: QUALITY ASSURANCE OF FINAL PRESSURE EQUIPMENT INSPECTION AND TESTING is amended as follows:

(i) in point 2, first subparagraph, the fourth indent is replaced by the following:

‘— a list of the harmonised standards, the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(ii) in point 5.1, second subparagraph, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(iii) in point 5.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(i) in Part 9: MODULE F: CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT VERIFICATION, point 4.1., the first subparagraph is replaced by the following:

‘All pressure equipment shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) or common specifications or equivalent tests shall be carried out in order to verify conformity with the approved type and described in the EU-type examination certificate and with the appropriate requirements of this Directive. In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’;

(j) Part 10: MODULE G: CONFORMITY BASED ON UNIT VERIFICATION is amended as follows:

(i) in point 2, third subparagraph, the fourth indent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications, have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(ii) in point 4, the first subparagraph is replaced by the following:

‘A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standard(s), and/or common specifications, and/or equivalent tests, to check the conformity of the pressure equipment with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out applying other technical specifications.’;

(iii) in point 4, second subparagraph, the second indent is replaced by the following:

‘— assess the materials used where these are not in conformity with the relevant harmonised standards or common specifications or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with point 4.3 of Annex I,’;

(k) Part 11: MODULE H: CONFORMITY BASED ON FULL QUALITY ASSURANCE is amended as follows:

(i) point 3.1, second subparagraph, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(ii) in point 3.1, second subparagraph, second indent, the fourth subindent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(iii) in point 3.2, third subparagraph, the second indent is replaced by the following:

‘— the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or common specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the pressure equipment will be met,’;

(iv) in point 3.3, first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(l) Part 12: MODULE H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION is amended as follows:

(i) in point 3.1, second subparagraph, the first indent is replaced by the following:

‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(ii) in point 3.1, second subparagraph, second indent, the fourth subindent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(iii) in point 3.2, third subparagraph, the second indent is replaced by the following:

‘— the technical design specifications, including standards, that will be applied and, where relevant harmonised standards or common specifications will not be applied in full, the means that will be used to ensure that the essential safety requirements of the Directive that apply to the pressure equipment will be met,’;

(iv) in point 3.3, second subparagraph, the first sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(v) in point 4.2, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer,’;

(vi) in point 4.2, third indent, the fourth subindent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive, where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(vii) in point 4.2, the fourth indent is replaced by the following:

‘— the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer or by another testing laboratory on his behalf and under his responsibility.’;

(viii) in point 4.3, first subparagraph, the second sentence is replaced by the following:

‘The certificate shall give the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design.’;

(3) Annex IV is amended as follows:

(a) point 1 is replaced by the following:

‘1. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative:’;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:’;

(c) point 7 is replaced by the following:

‘7. Where appropriate, the name, postal address, digital contact and number of the notified body which carried out the conformity assessment and the number of the certificate issued, and a reference to the EU-type examination certificate – production type, EU-type examination certificate – design type, EU design examination certificate or certificate of conformity.’.

ANNEX XIII

Annex II to Directive 2014/90/EU is amended as follows:

(1) Part I: Module B: EC-TYPE EXAMINATION is amended as follows:

(a) in point 3, second subparagraph, the first indent is replaced by the following:

‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, its name, postal address and digital contact as well’;

(b) in point 6, first subparagraph, the second sentence is replaced by the following:

‘The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(2) in Part II: Module D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS, point 3.1, second subparagraph, the first indent is replaced by the following:

‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, its name, postal address and digital contact as well’;

(3) in Part III: Module E: CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE, point 3.1, second subparagraph, the first indent is replaced by the following:

‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, its name, postal address and digital contact as well’.