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LIMITE

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| SIMPL 104 | TELECOM 308 |
| ANTICI 115 | POLCOM 250 |
| EF 292 | COMPET 896 |
| ECOFIN 1212 | ENV 861 |
| MI 670 | CLIMA 350 |
| ECO 33 | TRANS 394 |
| ENT 171 | ENER 450 |
| IA 128 | CODEC 1312 |
| IND 361 | |

NOTE

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| From: | General Secretariat of the Council |
| To: | Permanent Representatives Committee (Part 2) |
| No. prev. doc.: | 12523/25; 12524/25 |
| Subject: | <p>Omnibus IV</p> <p>Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) No 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 2023/11542 and (EU) 2024/1781 as regards digitalisation and common specifications</p> <p>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, 2014/1301/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</p> <p>- Mandate for negotiations with the European Parliament</p> |

I. BACKGROUND

1. The Commission put forward a fourth Omnibus package ('Omnibus IV') on 21 May 2025. It contains two proposals aiming to extend certain mitigating measures for small and medium-sized enterprises (SMEs) to small mid-cap enterprises (SMCs), two proposals regarding digitalisation and alignment of common specifications, and a 'stop-the-clock' proposal on

certain obligations regarding battery due diligence. This note concerns the proposal for a Regulation and a Directive on digitalisation and common specifications.

2. On digitalisation, the proposal follows up on a broader strategy to prioritise digital formats with the aim of eliminating paper-based requirements in product legislation. In particular, the proposal foresees the digitalisation of the EU declaration of conformity, as well as the exchanges between competent national authorities and economic operators. The proposal additionally gives the possibility for manufacturers to provide instructions for use to end users in digital format in lieu of paper; it also foresees the insertion of a 'digital contact' in the manufacturer's information to be indicated on products placed on the market.
3. Furthermore, the proposal introduces alternative solutions to prove compliance of a product with EU rules via 'a common specification' in situations where harmonised standards do not exist or where they are insufficient.

II. STATE OF PLAY

4. The Antici Group on Simplification (AGS) met on 28 May, 4, 10, 16 and 25 June, 24 July and 1 and 11 September to examine the Commission proposals and prepare Presidency compromise texts. Following a swift procedure applied with the utmost priority by both co-legislators, the 'stop-the-clock' text on certain battery due diligence obligations was adopted by the Council on 18 July 2025¹.

III. KEY COMPROMISE ELEMENTS

5. Upon request of delegations, the Presidency deleted the proposed amendments to the Regulation on requirements for accreditation and market surveillance relating to the marketing of products, as it is not a product-related regulation and was therefore considered out of scope.
6. For common specifications, in response to the request of delegations, the Presidency aligned the text with the approach agreed in the Toy Safety Regulation² (Article 14) earlier this year. The compromise text makes it clear that the common specifications should only serve as a fallback option when harmonised standards are not available or insufficient.

¹ PE-CONS 28/1/25 REV 1.

² ST 10091/25.

7. On digitalisation, the Presidency introduced further clarifications regarding the access to digitally available information and to a company's 'digital contact'. It is also ensured that in cases where there is a risk of serious harm to consumers, safety information is always available in paper form.
8. The deadline to transpose amendments to the Directive was extended to 24 months.
9. Finally, one delegation requested to include an additional amendment to the Ecodesign for Sustainable Products Regulation³ to prolong the validity of the transitional continued application of Directive 2009/125/EC⁴ for a number of product groups by two years to 31 December 2028. The proposal received support from several delegations and the Presidency therefore proposes to include it in the compromise text.
10. The Presidency compromise text on the Regulation is set out in Annex I and the Presidency compromise text on the Directive is set out in Annex II. Changes compared to the Commission proposal are marked in **bold**, deletions in ~~strike through~~.

IV. CONCLUSION

11. The Permanent Representatives Committee is invited to agree on a mandate with regard to the proposed Regulation and Directive, as set out in the Annexes to this note, and to invite the Presidency to conduct negotiations with the European Parliament on the basis of this mandate.
12. In accordance with the approach to legislative transparency endorsed by Coreper on 14 July 2023, and in full consistency with Regulation (EC) 1049/2001 and the Council's Rules of Procedure, the text of the mandate thus agreed will be made public unless the Permanent Representatives Committee objects.

³ Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC.

⁴ Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products.

2025/0134 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations ~~(EU) No 765/2008~~, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 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 Committee⁵,

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 their intended

⁵ OJ C , , p. .

purpose 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 2030’⁶, 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-⁶, 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, **harmonisation** 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 **or require an excessive burden for the economic operators**. 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. **A smooth transition should be pursued.**
- (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 Regulations (EU) 2016/424⁷, (EU) 2016/425⁸, (EU) 2016/426⁹,

⁶ https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en.

⁷ Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/424/oj>).

⁸ Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51, ELI: <http://data.europa.eu/eli/reg/2016/425/oj>).

⁹ Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99, ELI: <http://data.europa.eu/eli/reg/2016/426/oj>).

(EU) 2023/1230¹⁰, (EU) 2023/1542¹¹ and (EU) 2024/1781¹² of the European Parliament and of the Council (the ‘Regulations concerned’). The Regulations concerned are based on the principles of the ‘new approach’ to technical harmonisation and are aligned with the reference provisions laid down in Decision No 768/2008/EC of the European Parliament and of the Council¹³.

- (6) In accordance with the Regulations concerned, manufacturers are to draw up an EU declaration of conformity stating that the fulfilment of essential requirements set out in the applicable Regulations 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, Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, and (EU) 2023/1230 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 ~~electronically~~ accompany the product **in electronic form**. The manufacturer ~~will make sure~~ **should therefore ensure** that the EU declaration of conformity is **directly** accessible through an internet address or a machine-readable code, **free of charge, without the need for providing any personal data, downloading or using additional applications specific to the economic operator or the obligation to register solely to access the EU declaration of conformity**.

¹⁰ Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and amending Directive (EU) 2021/647 (OJ L 165, 29.6.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/1230/oj>).

¹¹ Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/1542/oj>).

¹² Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (OJ L 281, 28.6.2024, p. 1, ELI: <http://data.europa.eu/eli/reg/2024/1781/oj>).

¹³ 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](http://data.europa.eu/eli/dec/2008/768(1)/oj)).

- (8) Taking into account that in 2024 no less than 94% of EU households had access to internet¹⁴, the paper format of the instructions accompanying the products under the scope of the Regulations concerned is ~~outdated~~**becoming less important** and not aligned with ~~the~~ current technologies, the ~~practice~~**practices** of consumers ~~nor with~~ **the** green objectives. Consequently, the possibility for a digital format of the instructions should be introduced in the Regulations concerned. This will allow manufacturers to provide 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~~**specific safeguards for** consumers **should ensure that they, as non-professional users, are still able to access and understand the information, in contrast to professional users, who are expected to possess the expertise and knowledge necessary for the correct use and handling of products.** ~~the~~ Safety information, including instructions having ~~an~~ impact on ~~product~~ safety, ~~should~~**the safe use of the products, might** be provided **in digital format where a product is used solely by professional users, namely persons acquiring the product as professional end users in the course of their industrial or professional activities.** However, where it is reasonably foreseeable that a product, even if primarily intended for professional use, could also be used by consumers, manufacturers should provide the safety information in paper format or ~~marked~~**mark** it directly on the product. The definition of ‘consumer’ forms part of the notion of ‘end user’ as laid down in Regulation (EU) 2019/1020 of the European Parliament and of the Council¹⁵, which applies to the Regulations concerned, and refers to any natural person acting for purposes outside their trade, business, craft or profession. This requirement ensures that all consumers, including vulnerable consumers such as elderly persons, persons with disabilities or those with limited digital literacy, are able to access and understand the safety information. Such information should therefore be easily visible and legible, thereby guaranteeing a high level of consumer protection and safeguarding public safety. Instructions and safety information provided in digital format should be directly accessible in particular by taking into account the

¹⁴ ~~Source: Digital economy and society statistics—households and individuals—Statistics Explained.~~

¹⁵ **Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1, ELI: <http://data.europa.eu/eli/reg/2019/1020/oj>).**

requirements set out in Annex I of Directive (EU) 2019/882 of the European Parliament and of the Council¹⁶, insofar as the products fall within the scope of that Directive, so as to ensure usability by all end-users, including persons with disabilities. Instructions and safety information should be directly accessible through an internet address or a machine-readable code, free of charge, without the need for providing any personal data, downloading or using additional applications specific to the economic operator or the obligation to register solely to access the instructions and safety information. This is in line with the overarching vision of digital inclusion, as set out in the European Declaration on Digital Rights and Principles for the Digital Decade, notably chapter II on Solidarity and inclusion. 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.

(8a) Regulation (EU) 2016/425 contains certain sectoral specificities. In order to protect the safety of consumers, where the product is intended for, or can be reasonably foreseen to be used by, consumers, all the instructions and information set out in point 1.4 of Annex II, which are related to the safe use of the product, should be provided in a paper format or made visible on the packaging

(9) 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 a digital contact should be defined in the Regulations concerned. **The digital contact should allow consumers and competent authorities to contact economic operators directly, and should be accessible free of charge, without the need for providing any personal data, downloading or using additional applications specific to the economic**

¹⁶ Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (OJ L 151, 7.6.2019, p. 70, ELI: <http://data.europa.eu/eli/dir/2019/882/oj>).

operator or the obligation to register solely to contact the economic operator. Such digital contact may include, for example, an email address or other direct means of digital communication without intermediate steps and allowing for traceability of exchanges. However, it should not be understood as encompassing automatic replies to queries, chatbots, fax numbers, or telephone lines. The term ‘digital contact’, similarly to the term ‘electronic address’ in Regulation (EU) 2023/988 of the European Parliament and of the Council¹⁷, should be interpreted in a technologically neutral manner, capable of evolving with future technological developments, and should cover all forms of direct digital communication.

- (10) The Regulations concerned require that economic operators provide, ~~on~~^{upon} a reasoned request from a competent national authority, all information and documentation necessary to demonstrate the conformity of the concerned products with the respective Regulations, in paper or electronic form. The paper-based form is ~~an outdated requirement~~^{becoming less important}, 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, **in particular SMEs**, 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.
- (11) The current Union standardisation framework, which is based on Regulation (EU) No 1025/2012 of the European Parliament and of the Council¹⁸, represents the framework by

¹⁷ **Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L 135, 23.5.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/988/oj>).**

¹⁸ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European

default to elaborate standards that provide for a presumption of conformity with the relevant essential health and safety ~~or other~~ requirements **of the Regulations concerned**. However, ~~where no~~ **in the absence of relevant references to** 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 **of the Regulations concerned, provided that in doing so it duly respects the role and functions of the European standardisation organisations**, as an exceptional fall-back solution to facilitate the manufacturer's obligation to comply with those health and safety ~~or other~~ requirements **of the Regulations concerned**.

- (12) As the digital product passport is foreseen in certain ~~EU~~ **Union** legislation, such as Regulation (EU) 2023/1542 **of the European Parliament and of the Council**¹⁹, it is essential to require economic operators to store the information contained in the EU declaration of conformity and instructions 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 - **such as declarations of conformity - required under the various pieces of product legislation that may apply to the same product, thereby upholding the principle of a single declaration of conformity. In addition, instructions provided in electronic form would be stored together with the declaration of conformity**. 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 it aligns with the principle that where several pieces of Union harmonisation legislation apply to a product, the manufacturer or other economic operator, where appropriate, should provide a single EU declaration of conformity.

Parliament and of the Council (OJ L 316, 14.11.2012, p. 12, ELI: <http://data.europa.eu/eli/reg/2012/1025/oj>).

¹⁹ **Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/1542/oj>).**

- (12a) **To ensure regulatory continuity and to allow sufficient time for the adoption of certain acts identified under Article 79 of Regulation (EU) 2024/1781 of the European Parliament and of the Council, it is appropriate to prolong the validity of the transitional continued application of Directive 2009/125/EC until 31 December 2028. This will also support a coherent and effective transition towards the new digital instruments established under the Regulation, in particular the Digital Product Passport.**
- (13) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as this Regulation amends Regulations which are harmonising products legislations but can rather by reason of better harmonisation of EU applicable rules to products, be achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (14) To ensure a smooth and effective transition, to minimize disruptions, and to provide a reasonable timeframe for industries to adjust to the new requirements amendments to Regulations ~~(EU) 765/2008~~, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009, (EU) 2023/1542 and (EU) 2024/1781 concerning digitalisation should be deferred. Amendments to Regulation (EU) 2023/1230 should apply from the date of application of that Regulation.
- (15) In order to enable economic operators to supply stock of products that have been placed on the market before the date of application of amendments to Regulations (EU) ~~765/2008~~, ~~(EU) 2016/424~~, (EU) 2016/425, (EU) 2016/426, ~~(EU) 2019/1009~~, (EU) 2023/1542 and (EU) 2024/1781 concerning digitalisation, 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 those Regulations in their version applicable before that date.
- (16) Regulations ~~(EU) 765/2008~~, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, ~~(EU) 2019/1009~~, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 765/2008

Regulation (EU) 765/2008 is amended as follows:

(1) Article 2 is amended as follows:

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

‘(9a) ‘a common specification’ means a set of technical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a product, device, service, process or system;’²

(b) paragraph 10 is replaced by the following:

‘10. ‘accreditation’ shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards or common specifications and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity;’²

(2) in Article 10, paragraph 5 is replaced by the following:

‘5. Peer evaluation shall ascertain whether the national accreditation bodies meet the requirements laid down in Article 8, taking into account the relevant harmonised standards or common specifications referred to in Article 11;’²

(3) in Article 11, paragraph 1 is replaced by the following:

‘1. National accreditation bodies that demonstrate conformity with the criteria laid down in the relevant harmonised standard, the reference of which has been published in the Official Journal of the European Union, or with the criteria laid down in common specifications, by having successfully undergone peer evaluation under Article 10 shall be presumed to fulfil the requirements laid down in Article 8.’²

Article 2

Amendments to Regulation (EU) 2016/424

Regulation (EU) 2016/424 is amended as follows:

(1) Article 3 is amended as follows:

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

‘(17a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~ **contacted** without the need to register or to download an application; **or use additional applications specific to the economic operator;**’

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

‘(19a) ‘common ~~specifications~~ **specification**’ means a ~~set of~~ technical ~~requirements~~ **specification**, other than a standard, that provide means of complying with the essential requirements **set out in Annex II** applicable to a ~~product, device, service, process or system;~~ **subsystem or safety component;**’

(2) Article 11 is amended as follows:

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

‘Where compliance of a subsystem or a safety component with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity **referred to in Article 19**, in electronic form, and affix the CE marking **referred to in Article 20.**;’

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

‘Changes in subsystem or safety component design or characteristics and changes in the harmonised standards or in the common specifications or in other technical specifications by reference to which the conformity of the subsystem or the safety component 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 subsystem or the safety component 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 subsystem or safety component. The postal address and digital contact shall indicate a single point through which the manufacturer can be ~~reached~~**contacted**.;’

- (d) paragraph 7 is replaced by the following:

‘7. Manufacturers shall ensure that the subsystem or the safety component is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed and by the instructions and safety information, in a language which can be easily understood by ~~end-users~~**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~~**user** of the ~~products~~**subsystem or the safety component** when deciding the specific format for the instructions and safety information. When drafting **instructions and** the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the ~~end-user~~**user**, as well as the role which the instructions play for ensuring safety.

However, where a large number of subsystems or safety components are delivered to a single economic operator or ~~end-user~~**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 **directly** accessed.

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

- (a) mark on the subsystem or the safety component, or, where that is not possible, on its packaging or in an accompanying document, how to **directly** access them and how to request them in paper format;
- (b) present them in a format that makes it possible for the ~~end-user~~**user** to print and download the instructions **and safety information** and save them on an electronic device so that the ~~end-user~~**user** can access them at all times, in particular during a breakdown of the subsystem or the safety component; this requirement also applies where the instructions **and safety information** are embedded in the software of the subsystem or the safety component;
- (c) make them accessible online during the expected lifetime of the subsystem or the safety component and for at least 30 years after the placing on the market of the subsystem or the safety component.

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

- (e) paragraph 9 is replaced by the following:

‘9. 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 subsystem or the safety component with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have placed on the market.;

- (3) in Article 12(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 subsystem or the safety component;;’

(4) Article 13 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 subsystem or the safety component 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 **directly** accessed ~~and by the instructions and safety information~~ and, where appropriate, by other required documents, and that the manufacturer has complied with the requirements set out in Article 11(5) and (6).;’

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

‘Importers shall indicate on the subsystem or the safety component 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 subsystem or safety component.;’

- (c) paragraph 9 is replaced by the following:

‘9. –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 subsystem or a safety component, in a language which can be easily understood by that authority.– They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have placed on the market.;’

(5) Article 14 is amended as follows:

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

‘Before making a subsystem or a safety component available on the market, distributors shall verify that the subsystem or the safety component 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 **directly** accessed and by the instructions and safety information **in accordance with Article 11(7)** and, where appropriate, by other required documents, 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 11(5) and (6) and Article 13(3) respectively.;

(b) paragraph 5 is replaced by the following:

‘5. 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 subsystem or a safety component. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have made available on the market.;

(6) the following Article 17a is inserted:

‘Article 17a

Common Specifications

1. **In exceptional cases**, the Commission may ~~by means of~~**adopt** implementing acts ~~adopt establishing~~ common specifications that ~~enable compliance~~**provide a means to comply** with the essential requirements set out in Annex II ~~in any of~~. **Those implementing acts shall only be adopted where the following conditions are fulfilled:**

- (a) **there is no harmonised standard covering those** requirements ~~set out in Annex II~~ ~~are not covered by harmonised standards, or parts thereof, the references~~**the reference** of which ~~have been~~**is** published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**
- (b) ~~requirements set out in Annex II are covered by harmonised standards~~**the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more or parts thereof, the references of which have**

~~been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof result in non-compliance of a product with the essential for those requirements set out in Annex II; or; and:~~

- (1) the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
- (2) the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) are not delivered within the deadline set in the request;**
 - (b) do not comply with the request; or**
 - (c) do not satisfy the requirements they aim to cover.**
- ~~(e) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.~~

Those implementing acts shall be adopted in accordance with the ~~advisory examination~~ procedure referred to in Article 44(2)**44(3)**.

2. Subsystems and safety components that are in conformity with common specifications or parts thereof shall be presumed to be in conformity with essential requirements covered by those specifications or parts thereof, set out in Annex II.;
3. **Before preparing the draft of the implementing act referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**

5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

(7) in Article 18, paragraph 3 is replaced by the following:

- ‘3. Records and correspondence relating to the conformity assessment procedures shall be drawn up, in electronic form, in an official language of the Member State where the notified body carrying out the procedures referred to in paragraph 2 is established or in a language accepted by that body. 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 19, the following paragraph 5 is added:

- ‘5. Where other Union legislation applicable to ~~the~~ subsystem or a safety ~~component~~**components** 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 ~~in~~ Annex IX to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity required in Article 19, and the instructions and safety information** ~~and~~ referred to in Article 11(7), **where provided in electronic form**, shall be provided only in that digital product passport.’

- (9) in Article 26, paragraph 7, point (c) is replaced by the following:
- ‘(c) appropriate knowledge and understanding of the essential requirements set out in Annex II, of the applicable harmonised standards ~~or~~ **and** common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;’
- (10) in Article 34, paragraph 3 is replaced by the following:
- ‘3. Where a notified body finds that the essential 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 or approval decision.’
- (11) in Article 43(1), point (d) is replaced by the following:
- ‘(d) the subsystem or safety component is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed;’
- (12) Annexes III to IX are amended in accordance with Annex I to this Regulation.

Article 3

Amendments to Regulation (EU) 2016/425

Regulation (EU) No 2016/425 is amended as follows:

- (1) Article 3 is amended as follows:
- (a) the following point (8a) is inserted:
- ‘(8a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~ **contacted** without the need to register or to download an application; **or use additional applications specific to the economic operator;**’
- (b) the following point (10a) is inserted:

~~‘(10a) ‘common specifications’ means a set of technical requirements, other than a standard, that provides a means of complying with the essential requirements set out in Annex II applicable to a product, device, service, process or system the PPE;’~~
‘(10a) ‘common specification’ means a set of technical requirements, other than a standard, that provides a means of complying with the essential requirements set out in Annex II applicable to a product, device, service, process or system the PPE;’

(2) Article 8 is amended as follows:

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

‘Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU declaration of conformity referred to in Article 15, in electronic form, and affix the CE marking referred to in Article 16.’

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

‘Changes in the design or characteristics of the PPE and changes in the harmonised standards, or in the common specifications, or in other technical specifications by reference to which the conformity of the PPE 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 PPE, 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 PPE. The postal address and digital contact shall indicate a single point through which the manufacturer can be ~~reached~~**contacted**.’

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

‘7. Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II, 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 may be provided in electronic form. Such instructions and information, as well as any labelling, shall be clear, understandable, intelligible and legible.’

The manufacturer shall take into account the intended use and the foreseeable end-user of the PPE when deciding the specific format for the instructions and information set out in point 1.4 of Annex II.

In the case of PPE 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 make them visible on the packaging, the instructions and information set out in point 1.4 of Annex II, **which are related to the safe use of the PPE**. Such information shall be easily visible and legible for consumers.

When drafting the instructions and information set out in point 1.4 of Annex II, **which are related to the safe use of the PPE**, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user.

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

- (a) mark on the PPE, or, where that is not possible, on its packaging or in an accompanying document, how to **directly** 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 information** 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 PPE; this requirement also applies where the instructions **and information** are embedded in the software of the PPE;
- (c) make them accessible online during the expected lifetime of the PPE and for at least 10 years after the placing on the market of the PPE.

However, the end-user may, at time of the purchase of the PPE, or up to six months after that purchase, request the instructions and information set out in point 1.4 of Annex II in paper format. Where the end-user requests those instructions and information set out in point 1.4 of Annex II, the manufacturer

shall provide them to the end-user, free of charge, within one month of receiving the request.

8. The manufacturer shall provide the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed with the PPE.;

- (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 PPE with this Regulation, 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 the PPE;;’

- (4) Article 10 is amended as follows:

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

‘Importers shall indicate, on the PPE, their name, registered trade name or registered trademark as well as their postal address and digital contact through which they can be ~~reached or~~**contacted**, where that is not possible, on its packaging or in a document accompanying the PPE.;

- (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 PPE **with this Regulation** in a language which can be easily understood by that authority;;’

- (5) in Article 11(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 PPE.;

(6) the following Article 14a is inserted:

‘Article 14a

Common Specifications

1. **In exceptional cases**, the Commission may ~~by means of~~**adopt** implementing acts ~~adopt~~**establishing** common specifications **covering requirements that provide a means to comply with the**~~that enable compliance with~~ essential requirements set out in Annex II ~~in any of~~. **Those implementing acts shall only be adopted where the following casesconditions are fulfilled:**

(a) **there is no harmonised standard covering those** requirements ~~set out in Annex II are not covered by harmonised standards, or parts thereof, the reference~~**the reference** of which ~~have been~~**is** published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**

(b) ~~requirements set out in Annex II are covered by harmonised standards~~**the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof result in non-compliance of PPE with the**~~for those requirements set out in Annex II, or; and:~~

(1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**

(2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**

(a) **are not delivered within the deadline set in the request;**

(b) do not comply with the request; or

(c) do not satisfy the requirements they aim to cover.

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

Those implementing acts shall be adopted in accordance with the ~~advisory~~**examination** procedure referred to in Article 44(2)**44(3)**.

2. PPE that is in conformity with common specifications or parts thereof shall be presumed to be in conformity with the essential requirements **set out in Annex II**, covered by those **common** specifications or parts thereof, ~~set out in Annex II~~;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if**

appropriate, amend the implementing act establishing the common specification in question.’’

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

‘5. Where other Union legislation applicable to the PPE 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— **the instructions and information** in a digital product passport, the information required in Annex IX to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity required in Article 15,** and the instructions **and information** referred to in Article 8(7), **where provided in electronic form,** shall be provided only in that digital product passport.’

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

‘Where applicable, 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.’

(9) 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 II, of the applicable harmonised standards or common specifications, and of the relevant provisions of Union harmonisation legislation and of national legislation;’

~~(10) Article 25 is replaced by the following:~~

~~‘Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or common specifications or parts thereof the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in Article 24 in so far as the applicable harmonised standards cover those requirements.’~~

(11) In Article 32, 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 the corresponding harmonised standards, or common specifications, or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.’

(12) Annexes II, III, V, VII, VIII, and IX are amended in accordance with Annex II to this Regulation.

Article 4

Amendments to Regulation (EU) 2016/426

Regulation (EU) No 2016/426 is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (21a) is inserted:

‘(21a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~ **contacted** without the need to register or to download an application or **use additional applications specific to the economic operator;**’

(b) the following point (23a) is inserted:

‘(23a) ‘common ~~specifications~~ **specification**’ means a ~~set of~~ technical ~~requirements~~ **specification**, other than a standard, that provides a means of complying with the essential requirements **set out in Annex I** applicable to a ~~product, device, service, process or system;~~ **an appliance or a fitting.**’

(2) Article 7 is amended as follows:

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

‘Where compliance of an appliance or a fitting with the applicable requirements has been demonstrated by the 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 appliance or fitting design or characteristics and changes in the harmonised standards or in the common specifications or in other technical specifications by reference to which the conformity of the appliance or the fitting is declared shall be adequately taken into account.;

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

‘6. Manufacturers shall indicate on the appliance 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 appliance. The postal address and digital contact shall indicate a single point through which the manufacturer can be ~~reached~~**contacted**. The contact details shall be in a language easily understood by consumers and other end-users and the market surveillance authorities.

Manufacturers shall indicate on the fitting 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 fitting. The postal address and digital contact shall indicate a single point through which the manufacturer can be ~~reached~~**contacted**. The contact details shall be in a language easily understood by appliance manufacturers and the market surveillance authorities.

7. Manufacturers shall ensure that the appliance is accompanied by instructions and safety information in accordance with point 1.5 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 an electronic form. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

Manufacturers shall take into account the intended use and the foreseeable end-user of the ~~product~~**appliance** when deciding the specific format for the instructions and safety information.

In the case of ~~an appliance or fitting~~ 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 ~~equipment~~**appliance**, 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.

Manufacturers shall ensure that the fitting is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed and **that it is accompanied by** the instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I, in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned. The instructions may be provided in electronic form.

However, where a large number of fittings 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 **directly** accessed.

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

- (a) mark on the appliance ~~or fitting~~, or, where that is not possible, on its packaging or in an accompanying document, how to **directly** access them and how to **directly** 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 safety information** 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 appliance ~~or fitting~~;

- (c) make them accessible online during the expected lifetime of the appliance ~~or fitting~~ and for at least 10 years after the placing on the market of the appliance ~~or fitting~~.

However, the end-user may, at time of the purchase of the appliance ~~or fitting~~, 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 appliance or the fitting with this Regulation, 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 appliance or the fitting;;’

- (4) Article 9 is amended as follows:

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

‘They shall ensure that the manufacturer has drawn up the technical documentation, that the fitting bears the CE marking and is accompanied by the internet address and machine-readable code through which the EU declaration of conformity can be **directly** accessed and by, inter alia, instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I and that the manufacturer has complied with the requirements set out in Article 7(5) and (6).;’

(b) paragraph 3 is replaced by the following:

‘3. Importers shall indicate on the appliance 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 appliance. The contact details shall be in a language easily understood by consumers and other end-users and the market surveillance authorities.

Importers shall indicate on the fitting 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 fitting. The contact details shall be in a language easily understood by appliance manufacturers and the market surveillance authorities.’

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

‘Importers shall ensure that the fitting is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed and by, inter alia, the instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned.’

(d) 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 appliance or a fitting in a language which can be easily understood by that authority.’

(5) Article 10 is amended as follows:

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

‘Before making a fitting available on the market, distributors shall verify that the fitting 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 **directly** accessed, and by, inter alia, the instructions for incorporation or assembly,

adjustment, operation and maintenance in accordance with point 1.7 of Annex I in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned, and that the manufacturer and the importer have complied with the requirements set out in Article 7(5) and (6) and Article 9(3) respectively.;

- (6) 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 an appliance or a fitting.;

- (7) the following Article 13a is inserted:

‘Article 13a

Common Specifications

1. **In exceptional cases**, the Commission may ~~by means of~~**adopt** implementing acts ~~adopt~~**establishing** common specifications that ~~enable compliance with~~**provide a means to comply with the** essential requirements set out in Annex I ~~in any of~~. **Those implementing acts shall only be adopted where** the following ~~eases~~**conditions are fulfilled**:

- (a) **there is no harmonised standard covering those** requirements ~~set out in Annex I are not covered by harmonised standards, or parts thereof, the references~~**the reference** of which ~~have been~~**is** published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period**;
- (b) ~~requirements set out in Annex I are covered by harmonised standards~~**the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof result in non-compliance of appliances and fittings with the** ~~for those requirements set out in Annex I, or~~**and**:

- (1) the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or
- (2) the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:
 - (a) are not delivered within the deadline set in the request;
 - (b) do not comply with the request; or
 - (c) do not satisfy the requirements they aim to cover.
- (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.~~

Those implementing acts shall be adopted in accordance with the ~~advisory examination~~ procedure as ~~provided for~~ **referred to** in Article 42(2)**42(3)**.

2. Appliances and fittings that are in conformity with common specifications or parts thereof shall be presumed to be in conformity with the essential requirements covered by those **common** specifications or parts thereof, set out in Annex I;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts**

referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.

6. When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex I which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;

(8) Article 14 is amended as follows:

- (a) paragraph 4 is replaced by the following:

‘4. Records and correspondence relating to conformity assessment of an appliance or a fitting shall be drawn up, in electronic form, in an official language of the Member State where the notified body carrying out the procedures referred to in paragraphs 2 and 3 is established or in a language accepted by that body.’

- (b) 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 conformity assessment procedures in electronic form.’

(9) Article 15 is amended as follows:

- (a) paragraph 6 is replaced by the following:

‘6. The fitting shall be accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed.’

- (b) the following paragraph 7 is added:

‘7. Where other Union legislation applicable to an appliance or a fitting 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, **or as appropriate, the EU declaration of conformity required in Article 15**, and the instructions **and safety information** referred to in Article 7(7), **where provided in electronic form**, shall be provided only in that digital product passport.;

(10) 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~~**and** common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;;’

(11) 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 or approval decision.’

(12) in Article 40(1), point (f) is replaced by the following:

‘(f) the fitting is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed;;²

(13) Annexes III and V are amended in accordance with Annex III to this Regulation.

Article 5

Amendments to Regulation (EU) 2023/1230

Regulation (EU) 2023/1230 is amended as follows:

(1) in Article 3, the following point (22a) is inserted:

‘(22a)‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached~~

~~or engaged~~**contacted** without the need to register or to download an application ~~or~~
use additional applications specific to the economic operator;'

(2) Article 10 is amended as follows:

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

‘Where compliance of machinery or a related product with the essential health and safety requirements laid down in Annex III has been demonstrated by that conformity assessment procedure, manufacturers shall draw up the EU declaration of conformity, in digital format, in accordance with Article 21 and affix the CE marking in accordance with Article 24.;’

(aa) **in paragraph 6, the first sentence is replaced by the following:**

‘Manufacturers shall indicate their name, registered trade name or registered trade mark, and the postal address, website and e-mail address or other digital contact at which they can be contacted, on the machinery or related product or, where that is not possible, on its packaging or in a document accompanying the machinery or related product.;’

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

‘Manufacturers shall ensure that the machinery or related product is accompanied by the internet address or machine-readable code through which the EU declaration of conformity set out in Part A of Annex V can be **directly** accessed.;’

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

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the machinery or related products with this Regulation, in a language which can be easily understood by that authority.;’

(3) Article 11 is amended as follows:

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

‘Where compliance of partly completed machinery with the relevant essential health and safety requirements set out in Annex III has been demonstrated in the technical documentation set out in Part B, of Annex IV, manufacturers shall draw up the EU declaration of incorporation, in digital format, in accordance with Article 22.;

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

‘Manufacturers shall ensure that the partly completed machinery is accompanied by the internet address or machine-readable code through which the EU declaration of incorporation set out in Part B of Annex V can be **directly** accessed.;

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

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the partly completed machinery with this Regulation, in a language which can be easily understood by that authority.;

- (4) in Article 12(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the product within the scope of this Regulation;;’

- (5) in Article 13(9), the first sentence is replaced by the following:

‘9. Importers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate conformity of the machinery or related products with this Regulation in a language that can be easily understood by that authority.;

- (6) in Article 14(8), the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the partly completed machinery with this Regulation in a language that can be easily understood by that authority.;

(7) Article 15 is amended as follows:

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

‘(b) the machinery or related product is accompanied by the internet address or machine-readable code through which the EU declaration of conformity referred to in Article 10(8) can be **directly** accessed;’²

(b) in paragraph 6, the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the machinery or related product with this Regulation in a language that can be easily understood by that authority.’

(8) in Article 16(6), the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the partly completed machinery with this Regulation.’

(9) in Article 21, the following paragraph 5 is added:

‘5. Where other Union legislation applicable to machinery or related products 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 Parts A of Annex V to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity required in Article 21,** and the instructions **and information** referred to in Article 10(7), **where provided in digital format,** shall be provided only in that digital product passport.’

(10) in Article 22, the following paragraph 5 is added:

‘5. Where other Union legislation applicable to **partly completed** ~~machinery or related products~~ 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 incorporation or **assembly** instructions in a digital product passport, the information required in Parts B of Annex V to be included in the EU declaration of incorporation **or, as appropriate, the EU declaration of incorporation required in Article 22**, and the **assembly** instructions referred to in Article 11(7), **where provided in electronic form**, shall be provided only in that digital product passport.;

(11) in Article 25, the following paragraph 6 is added:

‘6. Where applicable, 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 digital format.;

(12) Annexes III, V, VII, IX, and X are amended in accordance with Annex IV to this Regulation.

Article 6

Amendments to Regulation (EU) 2023/1542

Regulation (EU) 2023/1542 is amended as follows:

(1) in Article 3 the following point (23a) is inserted:

‘(23a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~ **contacted** without the need to register or to download ~~an application or~~ **use additional applications specific to the economic operator;**’

(2) Article 17 is amended as follows:

(a) paragraph 4 is replaced by the following:

‘4. Records and correspondence relating to the conformity assessment procedures of batteries shall be drawn up, in electronic form, in the official language or languages of the Member State where the notified body carrying out the conformity assessment procedures is established, or in one or more languages accepted by that body.;

(b) 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 conformity assessment procedures in electronic form.;

(3) in Article 18(2), the third sentence is replaced by the following:

‘It shall be drawn up in electronic form.;

(4) Article 38 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. When placing a battery on the market or putting it into service, including for the manufacturers’ own purposes, manufacturers shall ensure that the battery:

(a) has been designed and manufactured in accordance with Articles 6 to 10 and Articles 12 and 14, and is, for stationary battery energy storage systems, accompanied by clear, understandable and readable instructions and safety information in a language or languages which can be easily understood by end-users, as determined by the Member State in which the battery is to be placed on the market or put into service; and

(b) is marked and labelled in accordance with Article 13.

The instructions and safety information for stationary battery energy storage systems may be provided in electronic form. In the case of stationary battery energy storage systems 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.

When the instructions **or safety information** are provided in electronic form, the manufacturer shall mark on the battery, or, where that is not possible, on its packaging or in an accompanying document, that they are accessible in the battery passport and how to request them in paper format.

The end-user may, at time of the purchase of the stationary battery energy storage systems, 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.;

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

‘Manufacturers shall indicate on the battery their name, registered trade name or registered trademark as well as their postal address and digital contact, indicating a single contact point.;

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

‘That information and documentation shall be provided in electronic form.;

- (5) in Article 39, the second sentence is replaced by the following:

‘That information and documentation shall be provided, in electronic form, free of charge.;

- (6) in Article 40(3), point (b) is replaced by the following:

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

- (7) Article 41 is amended as follows:

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

‘Importers shall indicate on the battery their name, registered trade name or registered trademark as well as their postal address and digital contact, indicating a single contact point.;

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

‘That information and the documentation shall be provided in electronic form.;

- (8) in Article 42(6), the second sentence is replaced by the following:

‘That information and the documentation shall be provided in electronic form.;

- (9) Annexes VIII, IX and XIII are amended in accordance with Annex V to this Regulation.

Article 7

Amendments to Regulation (EU) 2024/1781

Regulation (EU) 2024/1781 is amended as follows:

- (1) in Article 2, the following point (46a) is inserted:

‘(46a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached~~ **or engaged** ~~contacted~~ without the need to register or to download ~~an application~~; **or use additional applications specific to the economic operator;**’

- (2) in Article 24(2), the second sentence is replaced by the following:

‘Such information and documentation shall be provided, in electronic form, within 30 days of receipt of the request.;’

- (3) in Article 27(10), the second sentence is replaced by the following:

‘That information and documentation shall be provided, in electronic form, as soon as possible and in any event within 15 days of receipt of a request by that authority.;’

- (4) in Article 28(2), point (c) is replaced by the following:

‘(c) 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, in a language that can be easily understood by that authority as soon as possible and in any event within 15 days of receipt of such a request; and;’

- (5) in Article 29(8), the second sentence is replaced by the following:

‘That information and documentation shall be provided, in electronic form, as soon as possible and in any event within 15 days of receipt of a request by that authority.;’

- (6) in Article 30(5), first subparagraph, the second sentence is replaced by the following:

‘That information and documentation shall be provided, in electronic form, within 15 days of receipt of a request by that authority.;

- (6a) **in Article 36(2), second subparagraph, the second sentence is replaced by the following:**

‘That information shall be provided in electronic form within 15 days of receipt of a request by the market surveillance authority.’

- (6b) **in Article 79(1), point (a)(i) is replaced by the following:**

‘until 31 December 2028, as regards photovoltaic panels, space and combination heaters, water heaters, solid fuel local space heaters, air conditioners including air-to-air heat pumps and comfort fans, solid fuel boilers, air heating and cooling products, ventilation units, vacuum cleaners, cooking appliances, water pumps, industrial fans, circulators, external power supplies, computers, servers and data storage products, power transformers, professional refrigeration equipment and imaging equipment; ’

- (7) **in Annex V, point 2 is replaced by the following:**

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, the manufacturer’s authorised representative..’

Article 8

Transitional provision

Member States shall not impede the making available on the market of products which were placed on the market in accordance with Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1542 and (EU) 2024/1781 before ~~[OP: please insert...]~~ [24 months after **the date of** entry into force of this amending Regulation)].

Article 9

Entry into force and application

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

Article 7, point (6b), shall apply from ... [date of entry into force of this amending Regulation].

Article 5 and Annex IV shall apply from 20 January 2027.

The following provisions shall apply from ~~[OP: please insert 24...]~~ **[30 months after the date of entry into force of this amending Regulation]:**

- (a) Article 2, point(1)(a), point (2)(a), (c), (d) and (e), and points (3), (4), (5), (7), (8) and (11);
- (b) Article 3, point (1)(a), point (2)(a), (c), (d) and(e), and points (3), (4), (5), (7) and (8);
- (c) Article 4, point (1)(a), points (2)(a), (c) and (d), and points (3), (4), (5), (6), (8), (9) and (12);
- (d) ~~Articles 6 and 7~~**Article 6;**
- (da) Article 7, points (1), (2), (3), (4), (5), (6), (6a), and (7);**
- (e) Annex I, point (1)(a) and (c), point (2)(a), point (3)(a), point (4)(a), point (5)(a), (d) and (e), and point (7)(a);
- (f) Annex II, point (1)(a), point (3)(a), (c)(i) and (d)(i), point (4)(a), point (5)(a) and point (6)(a);
- (g) Annex III, point (1)(a)(i), (c), (e) and(g) and point (2)(a);
- (h) Annex V.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

Annexes III to IX to Regulation (EU) 2016/424 are amended as follows:

- (1) 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 4, points 4.2 and 4.3 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 that 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;
 - 4.3. 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;;
 - 4.3a. 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 Regulation;’**
 - (c) 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, any conditions for its validity, the necessary data for identification of the approved type (subsystem or safety component) and if relevant, descriptions of its functioning.;’

- (2) 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., 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.’~~
- (3) Annex V 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) point 4.1 is replaced by the following:

‘4.1. All subsystems or safety components 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 Regulation.

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.’
 - (c) point 5.2. is replaced by the following:

‘5.2. A random sample shall be taken from each lot. All the subsystems or safety components in the sample 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 their conformity with the approved type described in the EU-type examination certificate and with the applicable requirements of this Regulation and to determine whether the lot is accepted or rejected. 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.;

– (4) Annex VI 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., paragraph 1 is replaced by the following:

‘The notified body shall examine the technical documentation for the subsystem or the safety component and shall carry out the 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 subsystem or the safety component with the applicable requirements of this Regulation, 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.;

– (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 in full, the means, including other relevant technical specifications, that will be used to ensure that the essential requirements of this Regulation will be met;;’

(e) ~~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.;;’~~

(d) in point 3.6.2., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer;;’

(e) in point 3.6.3, first subparagraph, the second sentence is replaced by the following:

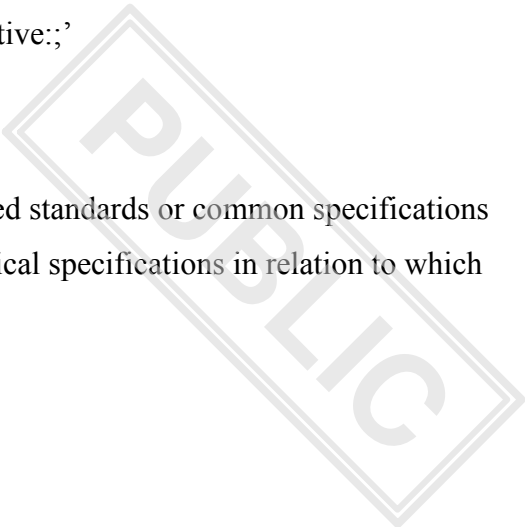
‘That certificate shall give the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design.;;’

– (6) in Annex VIII, point 2, point (c) is replaced by the following:

‘(c) a list of the harmonised standards referred to in Article 17, applied in full or in part, the references of which have been published in the Official Journal of the European Union, ~~or~~**and** a list of common specifications **referred to in Article 17a**, applied in full or in part, and where those harmonised standards or common specifications, have not been applied descriptions of the solutions adopted to meet the essential requirements of this Regulation 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) 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 II

Annexes II, III, V, VII, VIII, and IX to Regulation (EU) 2016/425 are amended as follows:

- (1) in Annex II, point 1.4 is amended as follows:
 - (a) in the first subparagraph, the first sentence is replaced by the following:

‘In addition to the name, postal address and digital contact of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:;’
 - (b) points (k) and (l) are replaced by the following:
 - ‘(k) references to the relevant harmonised standard(s) or common specification (s) used, including the date of the standard(s) or specification(s), or references to the other technical specifications used;
 - (l) the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed.;’
- (2) in Annex III, points (f) and (g) are replaced by the following:
 - ‘(f) the references of the harmonised standards referred to in Article 14 ~~or~~ **and** the common specifications referred to in Article 14a that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts which have been applied;
 - (g) where harmonised standards or common specifications have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;;’
- (3) Annex V 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, points (d) to (f) are replaced by the following:
- ‘(d) 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 technical specifications;
- (e) 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;
- (f) 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, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly.;’
- (c) point 6.2., is amended as follows:
- (i) point (b) is replaced by the following:
- ‘(b) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, the latter's name, postal address and digital contact;;’
- (ii) point (e) is replaced by the following:
- ‘(e) where harmonised standards or common specifications have been fully or partially applied, the references of those standards or specifications or parts thereof;;’

(d) point 7.6. is amended as follows:

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

‘(a) his name, postal address and digital contact and data identifying the EU type-examination certificate concerned;;’

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

‘(b) confirmation that there has been no modification to the approved type as referred to in point 7.2, including materials, sub-components or sub-assemblies, nor to the relevant harmonised standards or common specifications or other technical specifications applied;;’

– (4) Annex VII 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;;’

(b) point 4.3. is replaced by the following:

‘4.3. An adequate statistical sample of the manufactured PPE shall be selected by the notified body at a place agreed between the body and the manufacturer. All items of PPE of the sample shall be 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 the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.;’

– (5) Annex VIII 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) Annex IX 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, 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 III

Annexes III and V to Regulation (EU) 2016/426 are amended as follows:

- (1) Annex III is amended as follows:
 - (a) point 1.3.1. 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 (4) is replaced by the following:

‘(4) 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~~ and a list of common specifications, applied in full or in part, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Regulation, 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:

‘(e) 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) in point 1.4., points 1.4.3. and 1.4.4. are replaced by the following:

‘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 Regulation;;’
- (c) in point 1.6., 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, the necessary data for identification of the approved type, such as the type of gas, appliance category and gas supply pressure, and, if relevant, descriptions of its functioning.;’
- (d) In point 2.3, first subparagraph, the second sentence is replaced by the following:
- ‘An adequate sample of the final appliances or fittings 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 in order to check the conformity of the appliance or the fitting with the relevant requirements of this Regulation.;’
- (e) in point 3.3.1., 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;;’
- ~~(f) in point 3.3.3., 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) in point 4.3.1., 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;’
- (h) in point 4.3.3., 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.;’
- (i) point 5.4.1. is replaced by the following:
- ‘5.4.1. All appliances or fittings shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or common specifications, 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 Regulation.
- 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) point 5.5.2. is replaced by the following:
- ‘5.5.2. A random sample shall be taken from each lot in accordance with the requirements of point 5.5.3. All appliances or fittings in a sample 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 their conformity with the applicable requirements of this Regulation and to determine whether the lot is accepted or rejected. 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.;’
- (k) 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~~**and** a list of common specifications, applied in full or in part, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Regulation, 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.;

(1) 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 or common specifications and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the appliances or fittings with the applicable requirements of this Regulation, 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 V 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) paragraph 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 IV

Annexes III, V, VII, IX, and X to Regulation (EU) 2023/1230 are amended as follows:

- (1) Annex III is amended as follows:
 - (a) in point 1.7.4.2., point 1 is amended as follows:
 - (i) point (a) is replaced by the following:

‘(a) the business name, full postal address and digital contact of the manufacturer and, where applicable, of its authorised representative;,’
 - (ii) point (c) is replaced by the following:

‘(c) the EU declaration of conformity, or the internet address or ~~machine readable~~**machine-readable** code, through which the EU declaration of conformity can be **directly** accessed, in accordance with Article 10(8);,’
 - (b) point 4.3.1. is amended as follows:
 - (i) the first subparagraph is replaced by the following:

‘Each length of lifting chain, rope or webbing not forming part of an assembly shall bear a mark or, where this is not possible, a plate or irremovable ring bearing the name, postal address and digital contact of the manufacturer and the identifying reference of the relevant certificate.;’
 - (ii) point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer;,’
- (2) Annex V is amended as follows:
 - (a) in Part A, point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative.;’
 - (b) in Part B, point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative.;

– (3) Annex VII 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 an authorised representative, the name, postal address and digital contact of that authorised representative;;’

(b) in point 6.2., point (b) is replaced by the following:

‘(b) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;;’

(c) in point 7.6., point (a) is replaced by the following:

‘(a) its name, postal address and digital contact and data identifying the EU type-examination certificate concerned;;’

– (4) in Annex IX, 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 an authorised representative, the name, postal address and digital contact of that authorised representative;;’

– (5) Annex X is amended as follows:

(a) 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 an authorised representative, the name, postal address and digital contact of that authorised representative;.’

ANNEX V

Annexes VIII, IX and XIII to Regulation (EU) 2023/1542 are amended as follows:

- (1) in Annex VIII, Module D1:– Quality assurance of the production process, 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 manufacturer’s authorised representative, its name, postal address and digital contact as well;’
- (2) in Annex IX, point 2 is replaced by the following:

‘Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative;’
- (3) in Annex XIII, point 1, the following point (t) is added:
 - ‘(t) ‘clear, understandable and readable instructions for use in a format that makes it possible to print, download and save them on an electronic device so that the user can access them at all times, in particular during a breakdown of the battery (only for stationary battery energy storage systems).’

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 **and Article 100(2)** 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,

Having regard to the opinion of the Committee of the Regions¹,

Acting in accordance with the ordinary legislative procedure,

Whereas:

¹ **Opinion of ... (not yet published in the Official Journal).**

- (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~~ **their intended purpose** 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, **harmonisation** 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 **or require an excessive burden for the economic operators**. 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. **A smooth transition should be pursued.**
- (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/EC², 2011/65/EU³, 2013/53/EU⁴, 2014/29/EU⁵, 2014/30/EU⁶, 2014/31/EU⁷, 2014/32/EU⁸, 2014/33/EU⁹, 2014/34/EU¹⁰, 2014/35/EU¹¹,

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- ² 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>).
- ³ 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>).
- ⁴ 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>).
- ⁵ 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>).
- ⁶ 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>).
- ⁷ 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>).
- ⁸ 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>).
- ⁹ 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>).
- ¹⁰ 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>).
- ¹¹ 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>).

2014/53/EU¹², 2014/68/EU¹³ and 2014/90/EU¹⁴ of the European Parliament and of the Council ('the Directives concerned'). Most of the Directives **concerned** are based on the principles of the 'new approach' to technical harmonisation and are ~~also aligned to~~ **aligned with** the reference provisions laid down ~~by~~ **in** Decision No 768/2008/EC of the European Parliament and of the Council¹⁵.

- (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~~ **ensure** that the EU declaration of conformity is **directly** accessible through an internet address or a machine-readable code, **free of charge, without the need for providing any personal data, downloading or using additional applications specific to the economic operator or the obligation to register solely to access the EU declaration of conformity.**
- (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

¹² **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>).**

¹³ **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>).**

¹⁴ **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>).**

¹⁵ **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](http://data.europa.eu/eli/dec/2008/768(1)/oj)).**

the Directives concerned is ~~outdated~~ **becoming less important** and is not aligned with the current technologies, the ~~practice~~ **practices** of consumers ~~not with~~ green objectives. Consequently, the possibility for a digital format of the instructions should be introduced in the Directives. This will allow manufacturers to **provide** 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~~ **specific safeguards for consumers should ensure that they, as non-professional users, are still able to access and understand the information, in contrast to professional users, who are expected to possess the expertise and knowledge necessary for the correct use and handling of products.** the Safety information, including instructions having an impact on product safety, ~~should~~ **the safe use of the products, might be provided in digital format where a product is used solely by professional users, namely persons acquiring the product as professional end users in the course of their industrial or professional activities. However, where it is reasonably foreseeable that a product, even if primarily intended for professional use, could also be used by consumers, manufacturers should provide the safety information in paper format or marked** mark it directly on the product. The definition of ‘consumer’ forms part of the notion of ‘end user’ as laid down in Regulation (EU) 2019/1020 of the European Parliament and of the Council¹⁶, which applies to the Directives concerned, and refers to any natural person acting for purposes outside their trade, business, craft or profession. This requirement ensures that all consumers, including vulnerable consumers such as elderly persons, persons with disabilities or those with limited digital literacy, are able to access and understand the safety information. Such information should therefore be easily visible and legible, thereby guaranteeing a high level of consumer protection and safeguarding public safety. Instructions and safety information provided in digital format should be directly accessible in particular by taking into account the requirements set out in Annex I of Directive (EU) 2019/882 of the European Parliament and of the Council¹⁷,

¹⁶ Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1, ELI: <http://data.europa.eu/eli/reg/2019/1020/oj>).

¹⁷ Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (OJ L 151, 7.6.2019, p. 70, ELI: <http://data.europa.eu/eli/dir/2019/882/oj>).

insofar as the products fall within the scope of that Directive, so as to ensure usability by all end-users, including persons with disabilities. Instructions and safety information should be directly accessible through an internet address or a machine-readable code, free of charge, without the need for providing any personal data, downloading or using additional applications specific to the economic operator or the obligation to register solely to access the instructions and safety information.

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. **The digital contact should allow consumers and competent authorities to contact economic operators directly, and should be accessible free of charge, without the need for providing any personal data, downloading or using additional applications specific to the economic operator or the obligation to register solely to contact the economic operator. Such digital contact may include, for example, an email address or a contact form on a website. However, it should not be understood as encompassing automatic replies to queries, chatbots, fax numbers, or telephone lines. The term ‘digital contact’, similarly to the term ‘electronic address’ in Regulation (EU) 2023/988 of the European Parliament and of**

the Council¹⁸, should be interpreted in a technologically neutral manner, capable of evolving with future technological developments, and should cover all forms of direct digital communication.

- (11) The Directives concerned require that economic operators provide, ~~on~~**upon** 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~~**becoming less important**, 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, **in particular SMEs**, 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.

¹⁸ **Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L 135, 23.5.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/988/oj>).**

- (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 of the Directives concerned~~. However, ~~where no~~ **in the absence of relevant references to 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 **of the Directives concerned, provided that in doing to it duly respects the role and functions of the European standardisation organisations**, as an exceptional fall-back solution to facilitate the manufacturer's obligation to comply with those health and safety or other requirements **of the Directives concerned**.
- (14) As the digital product passport is foreseen in certain Union ~~legislations~~ **legislation**, such as Regulation (EU) 2023/1542 of the European Parliament and of the Council¹⁹, 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 - **such as declarations of conformity - required under the various pieces of product legislation that may apply to the same product, thereby upholding the principle of a single declaration of conformity. In addition, instructions provided in electronic form would be stored together with the declaration of conformity**. 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 it~~ **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.

¹⁹ **Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/1542/oj>).**

- (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 **to products**, 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~~**minimise** 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 **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~**contacted** without the need to register or to download ~~an application or~~ **use additional applications specific to the economic operator;**’

(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 **directly** 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 **directly** 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 **directly** 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 **directly** 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~~EU 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 **or, as appropriate, the EC declaration of conformity**, and the instructions referred to in Article 11(5), **where provided in electronic form**, 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 **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~ **contacted** without the need to register or to download ~~an application or use additional applications specific to the~~ **economic operator**;’

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

‘(13a) ‘common ~~specifications~~ **specification**’ means a ~~set of~~ technical ~~requirements~~ **specification**, other than a standard, that provides means of complying with the requirements **set out in Article 4** applicable to ~~a product, device, service, process or system~~; **an EEE**;’

(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~~ed~~**contacted**. 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 **or, as appropriate, 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. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt establishing~~ **common specifications covering requirements that provide a means to comply that enable compliance** with the ~~essential~~ requirements set out in Article 4 ~~in any of~~. **Those implementing acts shall only be adopted where the following ~~eases~~ conditions are fulfilled:**

(a) **there is no harmonised standard covering those requirements set out in Article 4** ~~are not covered by harmonised standards, or parts thereof, the~~

~~reference~~**the reference** of which ~~have been~~**is** published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**

- (b) ~~requirements set out in the Commission has requested, pursuant to Article 4 are covered by harmonised standards~~**10(1) of Regulation (EU) No 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of materials, components and EEE with the essential for those requirements set out in Article 4;; and:**

- (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
- (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**

- (a) **are not delivered within the deadline set in the request;**
- (b) **do not comply with the request; or**
- (c) **do not satisfy the requirements they aim to cover.**

- (e) ~~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~~**examination** procedure referred to in Article ~~19(3)~~**19(2)**.

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.;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article**

22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.

- 4. When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
- 5. Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
- 6. When a Member State considers that a common specification or parts thereof does not entirely satisfy the requirements set out in Article 4 which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

(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 **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~**contacted** without the need to register or to download ~~an application;~~**or use additional applications specific to the economic operator;**’

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

‘(20a) ‘common ~~specifications~~**specification**’ means a ~~set of~~ technical ~~requirements~~**specification**, other than a standard, that provide means of complying with the essential requirements **set out in Article 4(1) and Annex I** 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~~**contacted**.²;

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. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt establishing~~ common specifications **covering requirements that provide a means to comply** ~~that enable compliance~~ with the essential requirements set out in Article 4 ~~in any of~~ **4(1) and Annex I. Those implementing acts shall only be adopted where the following conditions are fulfilled:**
 - (a) **there is no harmonised standard covering those** requirements ~~set out in Article 4 are not covered by harmonised standards, or parts thereof, the reference~~ **the reference** of which ~~have been~~ **is** published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**
 - (b) ~~requirements set out in~~ **the Commission has requested, pursuant to Article 4** ~~are covered by harmonised standards~~ **10(1) of Regulation (EU) No 1025/2012,** ~~one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those~~ **standardisation organisations to draft or to revise European standards** ~~or parts thereof results in non-compliance of products with the essential~~ **for those requirements set out in Article 4; or; and:**
 - (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**

- (b) do not comply with the request; or**
- (c) do not satisfy the requirements they aim to cover.**
- ~~(e) 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~~**examination** procedure referred to in Article ~~50(2)~~**50(3)**.

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 ~~44(1)~~ **and Annex I**;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Article 4(1) and Annex I which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and**

may, if appropriate, amend the implementing act establishing the common specification in question.’;

(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 **directly** 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 **or, as appropriate, the EU declaration of conformity**, and the instructions **and safety information** referred to in Article 7(7), **where provided in electronic form**, shall be provided only in ~~the~~**that** 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 **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~ **contacted** without the need to register or to download an application; **or use additional applications specific to the economic operator;**’

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

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

(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 $PS \times V$ 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~~**contacted**.’

(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. **In exceptional cases, the Commission may, by means of adopt implementing acts, adopt establishing common specifications covering requirements that provide a means to comply that enable compliance with the essential safety requirements set out in Annex I in any of. Those implementing acts shall only be adopted where the following cases conditions are fulfilled:**
- (a) **there is no harmonised standard covering those requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the references the reference of which have been is published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;**
 - (b) **requirements set out in Annex I are covered by harmonised standards the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of vessels of which the product of $PS \times V$ exceeds 50 bar.L with the essential for those requirements set out in Article 4; or; and:**
 - (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the requirements they aim to cover.**
 - (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 $PS \times V$ exceeds 50 bar.L.**

Those implementing acts shall be adopted in accordance with the ~~advisory~~**examination** procedure referred to in Article ~~39(2)~~**39(3)**.

2. Vessels of which the product of $PS \times V$ exceeds 50 bar.L that are in conformity with the common specification shall be presumed to be in conformity with ~~the~~ essential **safety** requirements, covered by those common specifications or parts thereof, set out in Annex I;
3. **Before preparing the draft of the implementing act referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential safety requirements set out in Annex I which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

(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 **or, as appropriate, the EU declaration of conformity**, and the instructions **and safety information** referred

to in Article 6(7), **where provided in electronic form**, 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 **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~ **contacted** without the need to register or to download an application; **or use additional applications specific to the economic operator;**’
- (b) the following point (17a) is inserted:

‘(17a) ‘~~common specifications~~**specification**’ means a ~~set of technical requirements~~**specification**, other than a standard, that provide means of complying with the essential requirements **set out in Annex I** applicable to a ~~product, device, service, process or system~~**equipment**;’”

(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~~**contacted**.’

(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. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt establishing~~ **covering requirements that provide a means to comply that enable compliance** with the essential requirements set out in Annex I ~~in any of~~. **Those implementing acts shall only be adopted where** the following ~~eases~~ **conditions are fulfilled**:

- (a) ~~there is no harmonised standard covering those requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the reference of which have been published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;~~
- (b) ~~requirements set out in Annex I are covered by harmonised standards~~
the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of equipment with the essential
for those requirements set out in Annex I; or; and:
- (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
- (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
- (a) **are not delivered within the deadline set in the request;**
- (b) **do not comply with the request; or**
- (c) **do not satisfy the requirements they aim to cover.**
- (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~~**examination** procedure referred to in Article 41(2)**41(2a)**.

2. ~~Apparatus~~**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 Annex I.;

3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex I which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

(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 **or, as appropriate, the EU declaration of conformity**, and the instructions referred to in Article 7(7), **where provided in electronic form**, 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.;;’

(10a) in Article 41, the following paragraph is inserted:

‘2a. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.’;

(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 **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~ **contacted** without the need to register or

to download an application; or use additional applications specific to the economic operator;’

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

‘(11a) ‘common ~~specifications~~**specification**’ means a set of technical ~~requirements~~**specification**, other than a standard, that provide means of complying with the essential requirements **set out in Annex I** applicable to a ~~product, device, service, process or system~~**an instrument**;’

- (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~~**contacted**.’

- (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~~**instrument**, the information that is essential for ~~using it in a safe way~~**its intended use**. 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

1. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt establishing common specifications covering requirements that provide a means to comply that enable compliance~~ with the essential requirements set out in Annex I ~~in any of~~. **Those implementing acts shall only be adopted where the following conditions are fulfilled:**
 - (a) **there is no harmonised standard covering those** requirements set out in Annex I ~~are not covered by harmonised standards, or parts thereof, the reference~~ **the reference** of which ~~have been~~ is published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**
 - (b) ~~requirements set out in Annex I are covered by harmonised standards~~ **the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of instruments with the essential requirements set out in Annex I; and:**
 - (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the requirements they aim to cover.**
 - (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~~**examination** procedure referred to in Article 41(2)**41(3)**.

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;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex I which is covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

(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 **or, as appropriate, the EU declaration of conformity, and the** ~~and~~ **instructions and information** referred to in Article 6(7), **where provided in electronic form**, 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 **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~**contacted** without the need to register or to download an application; **or use additional applications specific to the economic operator;**’

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

‘(14a) ‘common ~~specifications~~**specification**’ means a ~~set of technical requirements~~**specification**, other than a standard **or a normative document**, that provide means of complying with the essential requirements **set out in Annex I and in the relevant instrument-specific Annexes** applicable to a ~~product, device, service, process or system~~**measuring instrument;**’

(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~~**contacted**.’

(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 **directly** 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~~**measuring instrument** 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~~**measuring instrument**, 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 **directly** 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 **directly** 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

1. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt establishing common specifications covering requirements that provide a means to comply 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~~ **implementing acts shall only be adopted where** the following ~~cases~~ **conditions are fulfilled**:
 - (a) **there is no harmonised standard and/or normative document covering those 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** ~~the reference~~ **of which have been** published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period**;
 - (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~~ **the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European Union, but application of these** **standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of measuring instruments with the essential** ~~for~~ **requirements set out in Annex I and in the relevant instrument-specific** **instrument specific Annexes covered by those parts of normative documents; or; and:**
 - (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**

(c) do not satisfy the requirements they aim to cover.

~~(e) 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~~**examination** procedure referred to in Article ~~46(2)~~**46(3)**.

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~~**Annex I and in the relevant instrument-specific Annexes** covered by those common specifications or parts thereof.;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard or normative document is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard or normative document.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex I and the relevant instrument-specific Annexes which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission**

shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;

(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 **or, as appropriate, the EU declaration of conformity**, and the

instructions **and information in accordance with point 9.3 of Annex I** referred to in Article 8(7), **where provided in electronic form**, 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 **directly** 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 **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~**contacted** without the need to register or to download an application; **or use additional applications specific to the economic operator;**’

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

‘(13a) ‘common ~~specifications~~**specification**’ means a ~~set of technical requirements~~**specification**, other than a standard, that provide means of complying with the essential **health and safety** requirements **set out in Annex I** applicable to a ~~product, device, service, process or system;~~**lift or a safety component for lifts;**’

(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 **directly** 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~~**contacted**.;’

(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 **directly** 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~~ **contacted**.’

- (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 **directly** 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 **directly** 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. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt establishing~~ **covering requirements that provide a means to comply** ~~that enable compliance~~ with the essential **health and safety**

requirements set out in Annex I ~~in any of~~. Those implementing acts shall only be adopted where the following ~~eases~~ conditions are fulfilled:

- (a) ~~there is no harmonised standard covering those requirements set out in Annex I~~ are not covered by harmonised standards, or parts thereof, the ~~reference~~ the reference of which ~~have been~~ is published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;
- (b) ~~requirements set out in Annex I~~ are covered by harmonised standards ~~the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those~~ standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of lifts and components for lifts with the essential ~~for those requirements set out in Annex I; or; and:~~
 - (1) the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or
 - (2) the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:
 - (a) are not delivered within the deadline set in the request;
 - (b) do not comply with the request; or
 - (c) do not satisfy the requirements they aim to cover.
- (e) ~~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~~ examination procedure referred to in Article ~~42(2)~~ 42(3).

2. Lifts and safety components for lifts that are in conformity with the common specification shall be presumed to be in conformity with essential **health and safety**

requirements, covered by those common specifications or parts thereof, set out in Annex I;

3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential health and safety requirements set out in Annex I which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

(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 **or, as appropriate, the EU declaration of conformity**, and the instructions referred to in Articles 7(7) and 8(7), **where provided in electronic form**, 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 **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~**contacted** without the need to register or to download ~~an application~~**or use additional applications specific to the economic operator**;’

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

‘(18a) ‘common ~~specifications~~**specification**’ means a ~~set of~~ technical ~~requirements~~**specification**, other than a standard, that provide means of complying with the essential **health and safety** requirements **set out in Annex II** 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 **directly** 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 **directly** 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~~**contacted**.;

- (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 **directly** 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 **directly** 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. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt establishing~~ **covering requirements that provide a means to comply that enable compliance** with the essential **health and safety** requirements set out in Annex II ~~in any of~~. **Those implementing acts shall only be adopted where the following casesconditions are fulfilled:**

- (a) **there is no harmonised standard covering those** requirements ~~set out in Annex II are not covered by harmonised standards, or parts thereof, the reference~~ **the reference** of which ~~have been~~ **is** published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**
- (b) ~~requirements set out in Annex II are covered by harmonised standards~~ **the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of products with the essential** ~~for those requirements set out in Annex II; or; and:~~

- (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**

- (2) the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:
- (a) are not delivered within the deadline set in the request;
 - (b) do not comply with the request; or
 - (c) do not satisfy the requirements they aim to cover.
- (e) ~~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 examination~~ procedure referred to in Article ~~39(2)~~**39(3)**.

2. Products that are in conformity with the common specification shall be presumed to be in conformity with essential **health and safety** requirements, covered by those common specifications or parts thereof, set out in Annex II.;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**

6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential health and safety requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

(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 **or, as appropriate, the EU declaration of conformity**, and the instructions **and safety information** referred to in Article ~~6(7)~~**6(8)**, **where provided in electronic form**, 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 **directly** 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 **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~**contacted** without the need to register or to download an application; **or use additional applications specific to the economic operator;**’
- (b) the following point (9a) is inserted:
- ‘(9a) ‘common ~~specifications~~**specification**’ means a ~~set of~~ technical ~~requirements~~**specification**, other than a standard, that provide means of complying with the safety objectives **referred to in Article 3 and set out in Annex I** applicable to a ~~product, device, service, process or system~~**electrical equipment**;;

(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~~ contacted.’

(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~~**electrical equipment**, 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. **In exceptional cases, the Commission may, by means of adopt implementing acts, adopt establishing common specifications covering requirements that provide a means to comply that enable compliance with the safety objectives referred to in Article 3 and set out in Annex I in any of. Those implementing acts shall only be adopted where the following conditions are fulfilled:**
- (a) **objectives referred to in Article 3 and set out in Annex I are not covered by there is no harmonised standards, or parts thereof, the references standard covering those safety objectives the reference of which have been published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;**
 - (b) **objectives referred to in the Commission has requested, pursuant to 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 10(1) of Regulation (EU) No 1025/2012, one or more European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of electrical equipment with the essential requirements set out in Annex II; or for those safety objectives; and:**
 - (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the safety objectives they aim to cover.**
 - (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~~**examination** procedure referred to in Article 23(3a)**23(2)**.

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;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1, or parts thereof which cover the same safety objectives as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the safety objectives referred to in Article 3 and set out in Annex I which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

(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 **or, as appropriate, the EU declaration of conformity**, and the instructions **and safety information** referred to in Article 6(7), **where provided in electronic form**, 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 **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~ **contacted** without the need to register or to download an application; **or use additional applications specific to the economic operator;**’

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

‘(18a) ‘common ~~specifications~~ **specification**’ means a ~~set of~~ technical ~~requirements~~ **specification**, other than a standard, that provide means of complying with the essential requirements **set out in Article 3** applicable to a ~~product, device, service, process or system~~ **radio equipment**;’²

(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~~ **contacted**.’

- (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 **directly** 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. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt establishing~~ common specifications **covering requirements that provide a means to comply that enable compliance** with the essential requirements set out in Article 3 ~~in any of~~. **Those implementing acts shall only be adopted where the following conditions are fulfilled:**
 - (a) **there is no harmonised standard covering those requirements set out in Article 3** ~~are not covered by harmonised standards, or parts thereof, the reference~~ **the reference** of which ~~have been~~ **is** published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**
 - (b) ~~requirements set out in~~ **the Commission has requested, pursuant to Article 3** ~~are covered by harmonised standards~~ **10(1) of Regulation (EU) No 1025/2012,** ~~one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of these~~ **standardisation organisations to draft or to revise European standards** ~~or parts thereof results in non-compliance of radio equipment with the essential~~ **for those requirements set out in Article 3; or; and:**
 - (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**

- (b) do not comply with the request; or**
- (c) do not satisfy the requirements they aim to cover.**
- ~~(e) 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~~**examination** procedure referred to in Article 45~~(2)~~**(3)**.

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.;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Article 3 which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if**

appropriate, amend the implementing act establishing the common specification in question.’;

(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~~**and** 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 **or, as appropriate, the EU declaration of conformity**, and the instructions **and safety information** referred to in ~~Article 10(8)~~ **Articles 10(8) and 10(10), where provided in electronic form**, 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 **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached or engaged~~ **contacted** without the need to register or to download ~~an application~~; **or use additional applications specific to the economic operator;**’

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

‘(24a) ‘common ~~specifications~~ **specification**’ means a ~~set of~~ technical ~~requirements~~ **specification**, other than a standard, that provide means of

complying with the essential requirements **set out in Annex I** applicable to a ~~product, device, service, process or system~~ **pressure equipment or assemblies;**”

(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~~ **contacted**.’

(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~~ **assemblies** 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. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt~~ **establishing** common specifications **covering requirements that provide a means to comply that enable compliance** with the essential **safety** requirements set out in Annex I ~~in any of~~. **Those implementing acts shall only be adopted where the following ~~eases~~conditions are fulfilled:**

(a) **there is no harmonised standard covering those** requirements ~~set out in Annex I~~ **are not covered by harmonised standards, or parts thereof, the**

~~reference~~**the reference** of which ~~have been~~**is** published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**

- (b) ~~requirements set out in Annex I are covered by harmonised standards~~**the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of pressure equipment or assemblies referred to in Article 4(1) and (2) with the essential**for those requirements set out in Annex I; ~~or; and:~~

(1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**

(2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**

(a) **are not delivered within the deadline set in the request;**

(b) **do not comply with the request; or**

(c) **do not satisfy the requirements they aim to cover.**

- (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~~**examination** procedure referred to in Article ~~44(2)~~**44(3)**.

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

3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential safety requirements set out in Annex I which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

(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 **or, as appropriate, the EU declaration of conformity**, and the instructions **and safety information** referred to in Article 6(7), **where provided in electronic form**, 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 **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached~~ **or engaged** ~~contacted~~ without the need to register or to download ~~an application~~; **or use additional applications specific to the economic operator;**’

- (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; ~~reached~~ **contacted**.;

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~~**contacted**.;

- (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 **the market or for the first time on board** ~~and~~ **any** 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 **or, as appropriate, the EU declaration of conformity, and** ~~and~~ **the instructions and the necessary information for safe installation on board and safe use of the product, including limitations of use, if**

any, referred to in Article 12(8)—, **where provided in electronic form**, 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...}~~ **[24 months after the date of 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...}~~ **[24 months after the date of entry into force of this amending Directive]**.

However, Member States shall apply the following provisions from ~~{OP: Please insert 24...}~~ **[30 months after the date of 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~~**Annex 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
The President

For the Council
The President

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~~**other technical** 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:

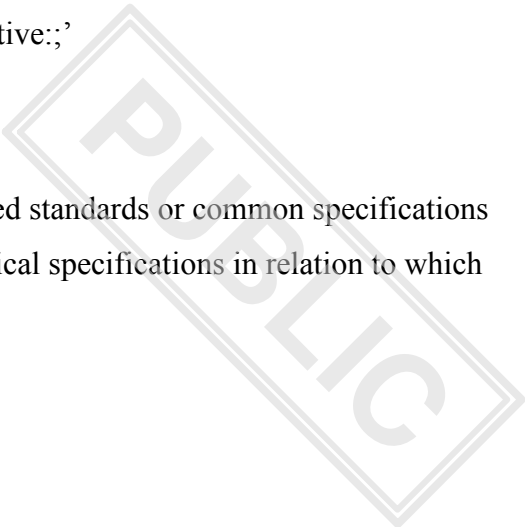
‘An adequate sample of the final vessels, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical 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:

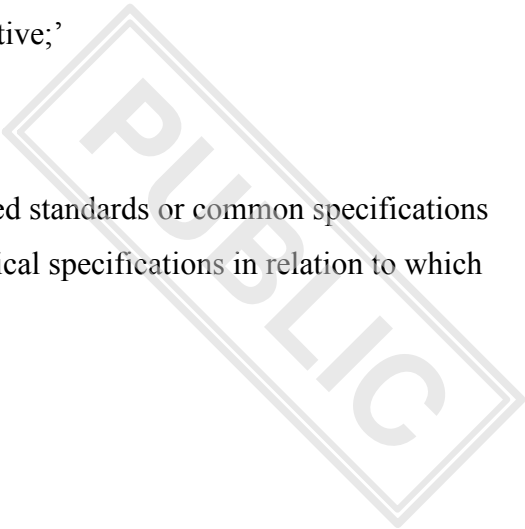
‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, or common specifications, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted 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 ~~Hand II~~ and 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~~ **is** 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~~**point** (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.’

