

Brussels, 26 September 2025
(OR. en)

13232/25

Interinstitutional File:
2025/0134 (COD)

SIMPL 110	TELECOM 324
ANTICI 121	POLCOM 265
EF 310	COMPET 915
ECOFIN 1241	ENV 890
MI 686	CLIMA 368
ECO 37	TRANS 409
ENT 177	ENER 461
IA 135	CODEC 1356
IND 373	

OUTCOME OF PROCEEDINGS

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	13018/25
No. Cion doc.:	9318/25 + ADD 1
Subject:	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 - Mandate for negotiations with the European Parliament

Delegations will find in the Annex, for information, the text of the mandate for negotiations with the European Parliament on the above-mentioned file as agreed by the Committee of Permanent Representatives at its meeting on 24 September 2025.

Changes compared to the Commission proposal are marked in **bold** and deletions in ~~strikethrough~~.

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 Committee¹,

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 purpose and to limit the administrative burden, it is important to streamline those requirements.

¹ OJ C , , p. .

- (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 Guidelines², 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.**

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

- (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) 2016/424³, (EU) 2016/425⁴, (EU) 2016/426⁵, (EU) 2023/1230⁶, (EU) 2023/1542⁷ and (EU) 2024/1781⁸ 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 Council⁹.
- (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.

³ 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>).

⁴ 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>).

⁵ 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>).

⁶ 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>).

⁷ 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>).

⁸ 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>).

⁹ 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)).

- (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**.
- (8) Taking into account that in 2024 no less than 94% of EU households had access to internet¹⁰, 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.**

¹⁰ ~~Source: Digital economy and society statistics – households and individuals – Statistics Explained.~~

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 Council¹¹, 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 requirements set out in Annex I of Directive (EU) 2019/882 of the European Parliament and of the Council¹², 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.

¹¹ 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>).

¹² 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>).

- (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 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 Council¹³, should be interpreted in a technologically neutral manner, capable of evolving with future technological developments, and should cover all forms of direct digital communication.**

¹³ **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>).**

- (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 Council¹⁴, represents the framework by 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**.

¹⁴ 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 Parliament and of the Council (OJ L 316, 14.11.2012, p. 12, ELI: <http://data.europa.eu/eli/reg/2012/1025/oj>).

- (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**¹⁵, 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.
- (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.**

¹⁵ **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>).**

- (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 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 II are covered by harmonised standards~~
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.**
- (c) ~~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~~ **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 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 ~~cases~~**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 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
~~requirements set out in Annex II, or; and:~~
for those

(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 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 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 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.****

- (c) ~~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 HV 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.

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;;’

(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 system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’~~²

(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, ~~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).’