PPE manufacturer's instructions and information : Good practice guidance (digital and printed form)

Version 1, dated 22/03/2024

Content

In separate document :

Appendix 1 : applicable quotes from relevant EU Commission guidelines
Appendix 2 : 'safety information' in EU legislation

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Preliminary notes

This good practice guide has been prepared by the secretariat and members of the European Safety Federation. Other stakeholders, such as concerned authorities, notified bodies and other trade organisations have been consulted, e.g. during a workshop organised on 19/02/2024.

The authors have prepared the document to the best of their knowledge and in good faith. The authors and/or their organisation or company cannot be held responsible if other interpretations than those reflected in the document are applied.
This document is under no circumstances legally binding.

While the term used in the legislation is “manufacturer’s instructions and information”, in practice this is often referred to as “user instructions (UI)” or “instructions for the user (IFU)”. In this document we use the term as used in the legislation (e.g. in the PPE Regulation).

Introduction

The purpose of this good practice guide is to **provide a common understanding** for manufacturers and all stakeholders, related to the manufacturer’s instructions and information **when provided in digital format**.

The PPE Regulation (EU) 2016/425[1] defines the requirements that must be met by the economic operators. Specifically, the obligations on the instructions and information, are included in article 8.7 (manufacturer), 10.4 (importer) and 11.2 (distributor). Requirements concerning the content are mainly included in Annex II point 1.4, completed with further requirements for specific cases throughout Annex II. The manufacturer has the sole and ultimate responsibility for the conformity of his PPE (including instructions and information), within the limits described further in this document (e.g. 1.1). **The Regulation does not specify that the manufacturer’s instructions and information need to be printed**.

Further information on the above mentioned parts of the Regulation is available in the relevant paragraphs of the PPE Regulation Guidelines (currently 3rd edition – October 2023)[2].

In paragraph 11.6. of the **PPE Regulation Guidelines there is no longer a mentioning of paper or printed format for the instructions** and information, as was the case in previous editions. Reference is made to section 3.1 of the **Blue Guide**[3] which in footnote 114 mentions the **possibility to provide the information on “electronic or other data storage format or even a website”**. However, the Blue Guide refers to **“safety information”** as included in a number of specific product legislative acts. For safety information the obligation to provide this **in printed format** is mentioned. It has to be remarked that the notion ‘safety information’ is not included in the PPE Regulation.

Concerning the manufacturer’s instructions and information, the PPE Regulation does not make the distinction between PPE destined for professional or private (consumer) use, nor

[1] 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 - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0425
[2] PPE Regulation Guidelines - Guide to application of Regulation EU 2016/425 on personal protective equipment 3rd edition - https://ec.europa.eu/docsroom/documents/56514
[3] The ‘Blue Guide’ on the implementation of EU product rules (edition June 2022) - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOC

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between the 3 risk categories for PPE. Therefore, this good practice guidance does not make these distinctions either. However, it has to be remarked that for professional use, the obligations as set out in Directive 89/656/EEC[4] concerning the use of PPE, remain applicable.

It has to be mentioned that manufacturers need to adopt the principles and legal acts related to the twin transition, meaning both “the European Green Deal” and “A Europe fit for the digital age”.

1. Requirements for manufacturer’s instructions and information for PPE

This section is applicable to **both digital and printed format**.

1.1. General

This section is not intended to be exhaustive, as both the PPE Regulation and the PPE guidelines already provide requirements and guidance. A number of key points are highlighted here to clarify the importance, whatever the format is.

There is **no difference in requirements** related to the content **between digital or printed** manufacturer’s instructions and information. If the instructions and information exist in both formats, both shall have the same information as required by the PPE Regulation and approved by the Notified Body.

The requirements for the marking of the PPE remains unchanged. These shall not be replaced by e-labelling. The marking needs to be explained in the manufacturer’s instructions and information, as per the requirement of annex II 1.4. (g) of the PPE Regulation.

The manufacturer’ instructions and information (in one language acceptable for type examination purposes) shall be approved by the Notified Body responsible for the EU Type Examination (module B – not applicable for category I PPE). Any change to the content of the instructions and information shall be approved by the same Notified Body.

For clarity, the use of pictograms, symbols and graphics, should be considered as much as possible.

The responsibilities of the manufacturer apply also to a natural or legal person or another economic operator who assembles, packs or labels ready-made PPE and places them on the market under his own trademark.

For traceability reasons, **a version reference or date shall be included** in the instructions and information.

[4] Council Directive of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (89/656/EEC) - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01989L0656-20191120&qid=1706267649778

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The PPE Regulation also requires the manufacturer to provide the Declaration of Conformity with the PPE. This can be through different means, in either printed or digital form.

1.2. Language

The manufacturer's instructions and information **shall be available at least in the official language of the Member States** where the product is sold. In Member States with more than one official language, the national legislation on language availability needs to be complied with.

The **manufacturer is responsible** to make the relevant translations and make the languages available. Both importer and distributor have a duty of care to check the availability of the necessary language(s) and have to act when necessary. This means, request the missing language versions from the manufacturer.

1.3. Availability

The manufacturer's instructions and information **shall accompany each single individual PPE, or at least the smallest commercial packaging** (including bulk packaging) of the PPE. This is valid for both digital and printed versions.

Whatever the format, the manufacturer's instructions and information, shall remain available for the foreseeable lifetime of the PPE and for at least 10 years after the placing on the market[5].

The manufacturer's instructions and information should be easily readable, e.g. font size, font type, contrast between background and text, colour of text have an influence on the readability, not only in printed format, but also when consulted on a screen.

1.4. Choice of format

It is the sole **responsibility of the manufacturer to choose the format (printed and/or digital**) for his instructions and information. The choice must be made taking into account the foreseeable use and/or users, as well as the technological evolution.

2. Additional guidance for digital manufacturer's instructions and information

2.1. The link to digital instructions and information and how it relates to the product

When the manufacturer's instructions and information are provided in **digital format**, the manufacturer **shall mark this clearly on the PPE itself or**, where this is not possible in view of the characteristics of the product, **on its smallest commercial packaging**. The operating instructions pictogram (ISO 7000-1641)[6] can be useful to indicate the link to the instructions.

[5] Inspired by the conditions for digital instructions as foreseen in the Machinery Regulation (EU)2023/1230
[6] See https://www.iso.org/obp/ui/#iso:grs:7000:1641

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The mode to access the digital user instruction shall be widely applicable.

Impractical or outdated mediums to store digital instructions and information, such as e.g. Floppy Disks, CD-ROM, are not acceptable forms, as access to the instructions and information needs to be readily available.

A link easily leading to the relevant internet page shall be provided, such that it can be read by the foreseeable users and other relevant parties as defined in the PPE Regulation on their common devices (personal computer, smartphone, tablet).

In 2024, a Data Matrix Code (i.e. a QR Code) can be a tool to lead to the relevant internet page.

The Data **Matrix Codes and/or the link shall be on the product itself, on a label attached to the product or on the smallest packaging**, following the requirements on marking of the PPE Regulation. However, it should be avoided by all stakeholders to put stickers over existing QR codes or links.

Providing both a QR code and a link, means that the manufacturer's instructions and information are accessible by scanning with a smartphone/tablet and by typing the link on a PC.

They also need to be visible and readable for all the foreseeable life time of the products, this means that, for example if a QR Code is on a product or a label, it should be legible at all times, meaning, it also needs to be proven durable as per the care or cleaning procedures prescribed by the manufacturer.

2.2. Access and legibility

Digital manufacturer's instructions and information **need to be easily available** for the end user in the applicable language[7] (e.g. foresee a language choice option).

The manufacturer shall **guarantee access at all times**. This means that the website needs to support high volume visits, in line with the foreseeable demand. In the event of peaks that may occur during an extraordinary event (e.g. health crisis, wildfire, earthquake, …), the manufacturer shall act as soon as possible to support the access for the increased volume.

No barrier (such as compulsory registration) shall be required to access it.

The manufacturer should provide his instructions and information in such a way that they are easily readable on different devices (smartphone, laptop, tablet, etc.). There must be download options to make them easily accessible offline.

The documents shall also be easily printable (e.g. not locked pdf document) and readable in the printed form.

The delivery formats have to be updated/evaluated to coincide and follow technological developments.

[7] See 1.2. of this good practice document

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It has to comply with any local accessibility or disability equality laws.

2.3. Printed version

At the request of the user at the time of the purchase, **the manufacturer shall provide** his instructions and information in **paper format free of charge** within one month[8]. This can be limited to the language version(s) requested and can be organized at the point of sales or through a simple request to the concerned manufacturer.

2.4. Availability of instructions and information

The manufacturer needs to ensure that the correct and applicable instructions and information are available and downloadable with the product, even if e.g. a website is renewed.

Effective systems and procedures shall be in place to ensure that users can be informed in case of updates or corrective actions with regard to those instructions and information.

The website where the instructions and information are made available must be protected against unauthorized access and tampering of the content.

To ensure that the user can make a reasoned selection of the correct PPE for the intended activity, the digital manufacturer's instructions and information, including the Declaration of Conformity, should be made available preferably prior to the purchase,. This is particularly helpful when the PPE is sold online.

3. Marking

3.1 General requirements

Generally, the **marking information is not impacted by the digital manufacturer's instructions** and information, but rather by the requirements included in the PPE Regulation and in specific standards.

As a general rule, marking is printed on or affixed to the PPE itself. In cases where the size or nature of the PPE does not allow this, exceptions are foreseen for the required marking to be provided on the packaging or in a printed document accompanying the PPE.

The marking or labelling require the following elements:

- CE marking;
- Name, registered trade name or registered trade mark of the manufacturer, including address;
- If applicable, name, registered trade name or registered trade mark of the importer; including address;
- Type, batch or serial number or other element allowing identification of the product;

[8] Inspired by the conditions for digital instructions as foreseen in the Machinery Regulation (EU)2023/1230

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- If applicable, batch, serial number, date of manufacture or date of obsolescence;
- Size designation;
- Identification of the specific applied product standard(s), including pictograms and levels of performance, if so required by the PPE Regulation (and then normally included in concerned product standards).
  e.g. PPE Regulation Annex II
  - 3.5, each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE;
  - 3.8.1, protection class or corresponding operating voltage;
  - 3.10.1, time limit for the storage of new filters
- Care labelling and/or qualification labelling, if required;
- Specific warning statements, such as risk for entanglement or snagging, typically required by the applied product standards (when PPE Regulation Annex II, 2.5 cannot be met).

3.2 Digital manufacturer's instructions and information

The link (whether QR code and/or weblink) **to the digital manufacturer's instructions and information shall be part of the labelling or marking** and should meet the same requirements, including for durability and readability.

4. Safety information

Even while the Blue Guide refers to the need to provide **"safety information"** in printed format, there is no definition nor in the Blue Guide, nor in any EU harmonised legislative act or guidance. In any case, the **PPE Regulation does not refer to safety information** but only to manufacturer's instructions and information. Therefore, this requirement needs to be inferred based on the General Product Safety Regulation (GPSR) (EU) 2023/988[9] and other directives and regulations where the terms have been used[10].

The GPSR requires that, **if the product** by itself under normal/reasonably foreseeable use could **present any new risk for the user**, safety information should be provided in a printed form on the product or in the accompanying documents (see previous paragraph 3).

This means for PPE, that the possible **new risks** related to the use of the PPE should be considered **independently from the protection** it is supposed to provide. Annex II point 1.2. of the PPE Regulation requires innocuousness (absence of risks and inherent nuisance factors, suitable materials, satisfactory surface condition), meaning that in principle, there should not be possible risks that lead to the need to provide safety instructions.

[9] 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 (Text with EEA relevance) - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2023.135.01.0001.01.ENG&toc=OJ%3AL%3A2023%3A135%3ATOC

[10] See appendix 1 to this good practice guidance

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Not providing appropriate protection in case of incorrect use (including care and maintenance) is not to be considered a risk caused by the PPE as the risk is pre-existing, independent of the use or non-use of the PPE.

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Appendix to :
PPE manufacturer's instructions and information :
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(digital and printed form)

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Content

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Appendix 1 : applicable quotes from relevant EU Commission guidelines

A1.1 PPE Regulation Guidelines (edition 10/2023)[1]

A1.1.1. Paragraph 3.1. (Article 8 – Obligations of the manufacturers)

The manufacturer has sole and ultimate responsibility for the conformity of his PPE with the applicable Union harmonisation legislation.

…

The manufacturers' instructions and information for use according to 8(7) has to be written in the language(s) decided by the Member States where the PPE is intended to be sold, the translation of such information must be provided by the manufacturer and/or his authorized representative established in the Union under his/their responsibility. Manufacturers are advised to check the language requirements with the national authorities concerned.

The manufacturer's instructions and information are one of the fundamental elements of any PPE and as such they have to be clear, concise, understandable and giving the appropriate information for the end users. It should be taken into account that the manufacturer's instructions and information may only be considered effective when they are easily perceived and understood, retained and appropriately used. Since the manufacturer's instructions and information provides the basis on which consumers can make a reasoned selection of appropriate PPE, it is also one of the means to increase the health and safety of the intended end user. High quality information minimises the risk of an incorrect selection and/or misuse. The better the quality of information, the easier the selection and correct use of the PPE will be.

The instructions for use shall accompany each single PPE, or each batch of identical products delivered to the same end user.

In order to enhance the manufacturer's instructions and information, the font size should be as large as possible to aid readers. The readability of text is also influenced by contrast between print colour and support and opacity of support.

A1.1.2. Paragraph 11.6. (Annex II 1.4. Manufacturer's instructions and information)

The manufacturer's instructions and information shall be checked, in terms of content and understanding, by the notified body when undertaking an EU type-examination.

A1.2 Blue guide (version published in OJEU 2022/C 247/01 on 29/06/2022)[2]

paragraph 3.1 Manufacturer

4. accompany the product with instructions and safety information ([110])([111])as required by the applicable Union harmonisation legislation ([112]), in a language easily understood by consumers and other end-users, as determined by the Member State concerned ([113]). Unless otherwise specified in specific legislation, instructions and safety information need to be provided ([114]), whether the product is intended for consumers or other end-users. This should include all the necessary information for the safe use of the product, to enable the consumer

[1] PPE Regulation Guidelines - Guide to application of Regulation EU 2016/425 on personal protective equipment 3rd edition - https://ec.europa.eu/docsroom/documents/56514

[2] The 'Blue Guide' on the implementation of EU product rules (edition June 2022) - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOC

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to assemble, install, operate, store, maintain, and dispose of the product. Instructions for assembly or installation should include the inventory parts and special skills or tools. Instructions on operation should include information for restriction of use, need for personal protective equipment, maintenance and cleaning or repair. It is for the manufacturer to determine the relevant information which should be included in the instructions and safety *information for a particular product. Manufacturers have to look beyond what they consider the intended use of a product and place themselves in the position of the average user of a particular product and envisage in what way they would reasonably consider to use the product. Furthermore, a tool designed and intended to be used by professionals only might also be used by non-professionals, the design and instructions accompanied must take this possibility into account. Instructions and safety information must be clear, understandable and intelligible;*

(110) The use of symbols according to international standards may be an alternative to written statements.
(111) In some specific cases, where several identical products are bundled and intended by the manufacturer to be sold together to the end- user or to be sold in a packaging for use in one application (e.g. installation equipment), it is sufficient to accompany the shipping unit with one set of instructions. However, if the bundle is dismantled and the different identical products sold individually, the economic operator dismantling the bundle and making available the individual products needs to make sure that a set of instructions and safety information accompanies each individual product.
(112) Not all Union harmonisation legislation requires both instructions and safety information since not all Union harmonisation legislation is safety related.
(113) The manufacturer, importer and distributor have the obligation to ensure that the product is accompanied by instructions in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. It is for each economic operator which makes available the product in a Member State, to ensure that all the required languages are available.
(114) Unless otherwise specified in specific legislation, whilst the safety information needs to be provided on paper, it is not required that all the set of instructions is also provided on paper but they can also be on electronic or other data storage format or even a website. Where this is the case, the full set of instructions must remain accessible for a reasonable period after the product was placed on the market depending on the intended use of the product. However, a paper version should always be available free of charge for the consumers who request it. The manufacturer must take account of the intended use and end users of the product when deciding the specific format for the instructions and safety information.

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Appendix 2 : 'safety information' in EU legislation

A2.1. Legislation with no or limited reference to 'safety information'

A2.1.1. No reference to instructions or safety information:

- The restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)[3]
- Ecodesign requirements for energy-related products (Directive 2009/125/EC and all implementing Regulations for specific product groups that have been adopted under this Framework Directive)[4]
- Aerosol Dispensers (Directive 75/324/EEC as amended)[5]
- Regulation on the Labelling of Tyres (Regulation (EU) 2020/740)[6]
- Emissions from non-road mobile machinery (Regulation (EU) 2016/1628)[7]
- Energy labelling (Regulation (EU) 2017/1369 and all delegated Regulations for specific product groups that have been adopted under this Framework Regulation and those adopted under Directive 2010/30/EU, the predecessor of Regulation 2017/1369)[8]

A2.1.2. Only reference to need for instructions or information which can be easily understood by end-users (no reference to safety information):

- Electromagnetic compatibility (Directive 2014/30/EU)[9]
- Measuring instruments (Directive 2014/32/EU)[10]
- Non-automatic weighing instruments (Directive 2014/31/EU)[11]
- Transportable Pressure equipment (Directive 2010/35/EU)[12]

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[3] Consolidated text: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011L0065-20230901&qid=1707742335652

[4] onsolidated text: Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009L0125-20121204&qid=1707742540019

[5] Consolidated text: Council Directive of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (75/324/EEC) - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01975L0324-20180212&qid=1707743026100

[6] Consolidated text: Regulation (EU) 2020/740 of the European Parliament and of the Council of 25 May 2020 on the labelling of tyres with respect to fuel efficiency and other parameters, amending Regulation (EU) 2017/1369 and repealing Regulation (EC) No 1222/2009 - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02020R0740-20200605&qid=1707743217230

[7] Consolidated text: Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R1628-20220717&qid=1707743416060

[8] onsolidated text: Regulation (EU) 2017/1369 of the European Parliament and of the Council of 4 July 2017 setting a framework for energy labelling and repealing Directive 2010/30/EU - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R1369-20210501&qid=1707743636546

[9] Consolidated text: Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02014L0030-20180911&qid=1707743811820

[10] Consolidated text: Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02014L0032-20150127&qid=1707743908896

[11] Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014L0031&qid=1707743990524

[12] Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32010L0035&qid=1707744181131

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- Lifts (Directive 2014/33/EU)[13]
- Marine equipment (Directive 2014/90/EU)[14]
- Noise emission in the environment by equipment for use outdoors (Directive 2000/14/EC)[15]
- Fertilising Products (Regulation (EU) 2019/1009)[16]
- Unmanned aircraft systems (Commission Delegated Regulation (EU) 2019/945)[17]

A2.1.3. Only reference to need for instructions and safety information which can be easily understood by end-users

- Cableway installations (Regulation (EU) 2016/424)[18]
- Radio equipment (Directive 2014/53/EU)[19]
- Pressure equipment (Directive 2014/68/EU)[20]
- Recreational craft (Directive 2013/53/EU)[21]
- Explosives for civil uses (Directive 2014/28/EU)[22]
- Pyrotechnic articles (Directive 2013/29/EU)[23]
- Electrical equipment designed for use within certain voltage limits (Directive 2014/35/EU)[24]

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[13] Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0033

[14] Consolidated text: Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02014L0090-20210811&qid=1707744532675

[15] Consolidated text: Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02000L0014-20190726&qid=1707744611468

[16] Consolidated text: Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02019R1009-20230316&qid=1707744715654

[17] Consolidated text: Commission Delegated Regulation (EU) 2019/945 of 12 March 2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02019R0945-20200809&qid=1707744869937

[18] Consolidated text: 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 - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R0424-20160331&qid=1707745503941

[19] Consolidated text: Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02014L0053-20231001&qid=1707745607826

[20] Consolidated text: Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02014L0068-20140717&qid=1707745682180

[21] Consolidated text: Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02013L0053-20131228&qid=1707745750407

[22] Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014L0028&qid=1707745819375

[23] Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013L0029&qid=1707745896948

[24] Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014L0035&qid=1707745965525

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EU Transparency Register number : 91447653655-65

A2.2 Legislation providing more information on 'safety information'

A2.2.1. General Product Safety Regulation (2023/988)[25]

Preamble 23

The safety of a product should be assessed taking into account all relevant aspects of the product, in particular its characteristics, such as the physical, mechanical and chemical characteristics, and its presentation, as well as the specific needs and risks which the product represents for certain categories of consumers who are likely to use the products, in particular children, older persons and persons with disabilities. ….. The safety of all products should be assessed taking into consideration the need for the product to be safe over its entire lifespan.

Preamble 33

Manufacturers should draw up technical documentation regarding the products they place on the market, which should contain the necessary information to prove that those products are safe. The technical documentation should be based on an internal risk analysis carried out by the manufacturer. The amount of information to be provided in the technical documentation should be proportionate to the complexity of the product and the possible risks identified by the manufacturer. In particular, manufacturers should provide a general description of the product and the elements necessary to assess its safety. In the case of complex products or products presenting possible risks, the information to be provided might need a more extensive description of the product. In such cases, an analysis of those risks and the technical means adopted to mitigate or eliminate the risks should also be included. Where the product complies with European standards or other elements applied to meet the general safety requirement laid down in this Regulation, the list of the relevant European standards or the other elements should also be indicated.

Preamble 58

…. Consumers should also be protected against dangerous products in the same way in the offline and online sales channels, including when purchasing products on online marketplaces. Building on the provisions of Regulation (EU) 2022/2065 concerning the traceability of traders, providers of online marketplaces should not allow a specific product offer to be listed on their platforms unless the trader has provided all information related to product safety and traceability as specified in this Regulation. Such information should be displayed together with the product listing so that consumers can benefit from the same information made available online and offline….

Article 3 Definitions

(2) 'safe product' means any product which, under normal or reasonably foreseeable conditions of use, including the actual duration of use, does not present any risk or only the minimum risks compatible with the product's use, considered acceptable and consistent with a high level of protection of the health and safety of consumers;

Article 6 Aspects for assessing the safety of products

[25] 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 - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R0988&qid=1707746375396

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VAT BE0454.000.382 – RPR Business Court Gent – Division Kortrijk
EU Transparency Register number : 91447653655-65

1 (d) the presentation of the product, the labelling, including the labelling regarding age suitability for children, any warnings and instructions for its safe use and disposal, and any other indication or information regarding the product;

Article 9 Obligations of manufacturers

7. Manufacturers shall ensure that their product is accompanied by clear instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market. That requirement shall not apply where the product can be used safely and as intended by the manufacturer without such instructions and safety information.

Article 19 Obligations of economic operators in the case of distance sale

(d) any warning or safety information to be affixed to the product or to the packaging or included in an accompanying document in accordance with this Regulation or the applicable Union harmonisation legislation in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market.

A2.2.2. Medical Device Regulation (EU)2017/745[26]

Article 2.1 Definitions

(14) 'instructions for use' means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken;

Article 7 Claims

In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trade marks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:
(a) ascribing functions and properties to the device which the device does not have;
(b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;
(c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;
(d) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

Article 10 Obligations manufacturers

11. Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

Annex I - Chapter II Requirements regarding design and manufacture
10.4 Substances
10.4.5. Labelling
Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 %

[26] Consolidated text: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20230320&qid=1707747116845

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EU Transparency Register number : 91447653655-65

weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use.

Annex I - Chapter II Requirements regarding design and manufacture
16. Protection against radiation
16.1. General

(a) Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.
(b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.

Annex I - Chapter III Requirements regarding the information supplied with the device
23. Label and instructions for use
23.1. General requirements regarding the information supplied by the manufacturer

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:
(a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.
(b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.
(c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio- frequency identification ('RFID') or bar codes.
(d) Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section.
(e) Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.
(f) Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation.
(g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.
(h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to

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EU Transparency Register number : 91447653655-65

the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.

Annex I - Chapter III Requirements regarding the information supplied with the device
23. Label and instructions for use
23.2. Information on the label

The label shall bear all of the following particulars:
…
(m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;

Annex I - Chapter III Requirements regarding the information supplied with the device
23. Label and instructions for use
23.4. Information in the instructions for use

The instructions for use shall contain all of the following particulars:
(a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2;
(b) the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate;
(c) where applicable, a specification of the clinical benefits to be expected.
(d) where applicable, links to the summary of safety and clinical performance referred to in Article 32;
(e) the performance characteristics of the device;
(f) where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories;
(g) any residual risks, contra-indications and any undesirable side- effects, including information to be conveyed to the patient in this regard;
(h) specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it;
(i) details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection;
(j) any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;
(k) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:
- *details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection,*
- *identification of any consumable components and how to replace them,*
- *information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and*
- *methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices;*

(l) if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use;
(m) if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation;
(n) if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no

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VAT BE0454.000.382 – RPR Business Court Gent – Division Kortrijk
EU Transparency Register number : 91447653655-65

longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses;
(o) an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements;
(p) if the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request;
(q) for devices intended for use together with other devices and/or general purpose equipment:
- *- information to identify such devices or equipment, in order to obtain a safe combination, and/or*
- *- information on any known restrictions to combinations of devices and equipment;*

(r) if the device emits radiation for medical purposes:
- *detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation,*
- *the means of protecting the patient, user, or other person from unintended radiation during use of the device;*

(s) information that allows the user and/or patient to be informed of any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate:
- *warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety,*
- *warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,*
- *warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,*
- *if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered,*
- *warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and*
- *precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user;*

(t) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra-indications, undesirable side-effects and risks relating to overdose;
(u) in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed;
(v) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate:
- *infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and*

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EU Transparency Register number : 91447653655-65

- *physical hazards such as from sharps.*

If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request;
(w) for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional;
(x) for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device;
(y) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;
(z) a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;
(aa) information to be supplied to the patient with an implanted device in accordance with Article 18;
(ab) for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

A2.2.3 Appliances burning gaseous fuels (Regulation (EU) 2016/426)[27]

Article 7 Obligations of manufacturers

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

Annex I
Preliminary observations 1.5.

All appliances shall:
(a) be accompanied by instructions for installation intended for the installer;
(b) be accompanied by instructions for use and servicing, intended for the user;
(c) bear appropriate warning notices, which shall also appear on the packaging.

A2.2.4 Simple pressure vessels (Directive 2014/29/EU)[28]

Article 6 Obligations of manufacturers

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

Annex I Essential Safety Requirements
4. Putting into service of the vessels

Vessels shall be accompanied by the instructions drawn up by the manufacturer, as referred to in point 2 of Annex III.

[27] 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 - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0426&qid=1707749796986

[28] Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014L0029&qid=1707750084561

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VAT BE0454.000.382 – RPR Business Court Gent – Division Kortrijk
EU Transparency Register number : 91447653655-65

Annex III Inscriptions, instructions, definitions and symbols

1.2. Vessels or their data plates shall bear at least the following information:
(a) the maximum working pressure (PS in bar);
(b) the maximum working temperature (Tmax in °C);
(c) the minimum working temperature (Tmin in °C);
(d) the capacity of the vessel (V in L);
(e) the name, registered trade name or registered trade mark and the address of the manufacturer;
(f) the type and serial or batch identification of the vessel

2. Instructions and safety information
The instructions shall contain the following information:
(a) the particulars given in point 1.2 except for the vessel's serial or batch identification;
(b) the intended use of the vessel;
(c) the maintenance and installation requirements for vessel safety

A2.2.5 Toys' safety (Directive 2009/48/EC)[29]

Article 4 Obligations of manufacturers

7. Manufacturers shall ensure that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned.

Article 10 Essential safety requirements

2. …
Labels affixed in accordance with Article 11(2) and instructions for use which accompany toys shall draw the attention of users or their supervisors to the inherent hazards and risks of harm involved in using the toys, and to the ways of avoiding such hazards and risks.

Article 11 Warnings

2. The manufacturer shall mark the warnings in a clearly visible, easily legible and understandable and accurate manner on the toy, on an affixed label or on the packaging and, if appropriate, on the instructions for use which accompany the toy. Small toys which are sold without packaging shall have appropriate warnings affixed to them. The warnings shall be preceded by the words 'Warning' or 'Warnings', as the case may be. Warnings which determine the decision to purchase the toy, such as those specifying the minimum and maximum ages for users and the other applicable warnings set out in Annex V, shall appear on the consumer packaging or be otherwise clearly visible to the consumer before the purchase, including in cases where the purchase is made on-line

A2.2.6 Machinery (Directive 2006/42/EC)[30]

Article 2 Definitions

(c) 'safety component' means a component:
- *which serves to fulfil a safety function,*

[29] Consolidated text: Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009L0048-20221205&qid=1707750541239
[30] Consolidated text: Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006L0042-20190726&qid=1707750855398

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VAT BE0454.000.382 – RPR Business Court Gent – Division Kortrijk
EU Transparency Register number : 91447653655-65

- *which is independently placed on the market,*
- *the failure and/or malfunction of which endangers the safety of persons, and*
- *which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.*

An indicative list of safety components is set out in Annex V,

Annex I
1. Essential health and safety requirements
1.1.2. Principles of safety integration

(c) When designing and constructing machinery and when drafting the instructions, the manufacturer or his authorised representative must envisage not only the intended use of the machinery but also any reasonably foreseeable misuse thereof.
The machinery must be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions must draw the user's attention to ways — which experience has shown might occur — in which the machinery should not be used.

Annex I
1. Essential health and safety requirements
1.7.4. Instructions

All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service.
The instructions accompanying the machinery must be either 'Original instructions' or a 'Translation of the original instructions', in which case the translation must be accompanied by the original instructions.
By way of exception, the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his authorised representative may be supplied in only one Community language which the specialised personnel understand.
The instructions must be drafted in accordance with the principles set out below.
1.7.4.1. General principles for the drafting of instruction
(a) The instructions must be drafted in one or more official Community languages. The words 'Original instructions' must appear on the language version(s) verified by the manufacturer or his authorised representative.
(b) Where no 'Original instructions' exist in the official language(s) of the country where the machinery is to be used, a translation into that/those language(s) must be provided by the manufacturer or his authorised representative or by the person bringing the machinery into the language area in question. The translations must bear the words 'Translation of the original instructions'.
(c) The contents of the instructions must cover not only the intended use of the machinery but also take into account any reasonably foreseeable misuse thereof.
(d) In the case of machinery intended for use by non-professional operators, the wording and layout of the instructions for use must take into account the level of general education and acumen that can reasonably be expected from such operators.

1.7.4.2. Contents of the instructions
Each instruction manual must contain, where applicable, at least the following information:
(a) the business name and full address of the manufacturer and of his authorised representative;
(b) the designation of the machinery as marked on the machinery itself, except for the serial number (see section 1.7.3);
(c) the EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature;
(d) a general description of the machinery;

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VAT BE0454.000.382 – RPR Business Court Gent – Division Kortrijk
EU Transparency Register number : 91447653655-65

(e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning;
(f) a description of the workstation(s) likely to be occupied by operators;
(g) a description of the intended use of the machinery;
(h) warnings concerning ways in which the machinery must not be used that experience has shown might occur;
(i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery is to be mounted;
(j) instructions relating to installation and assembly for reducing noise or vibration;
(k) instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators;
(l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;
(m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;
(n) the essential characteristics of tools which may be fitted to the machinery;
(o) the conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;
(p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately;
(q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;
(r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed;
(s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;
(t) the specifications of the spare parts to be used, when these affect the health and safety of operators;
(u) the following information on airborne noise emissions:

- *the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated,*
- *the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 µPa),*
- *the A-weighted sound power level emitted by the machinery, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A).*

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.
In the case of very large machinery, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery may be indicated.
Where the harmonised standards are not applied, sound levels must be measured using the most approapriate method for the machinery. Whenever sound emission values are indicated the uncertainties surrounding these values must be specified. The operating conditions of the machinery during measurement and the measuring methods used must be described.
Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at a height of 1,6 metres from the floor or access platform. The position and value of the maximum sound pressure must be indicated.
Where specific Community Directives lay down other requirements for the measurement of sound presssure levels or sound power levels, those Directives must be applied and the corresponding provisions of this section shall not apply;
(v) where machinery is likely to emit non-ionising radiation which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons

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EU Transparency Register number : 91447653655-65

1.7.4.3. Sales literature Sales literature describing the machinery must not contradict the instructions as regards health and safety aspects. Sales literature describing the performance characteristics of machinery must contain the same information on emissions as is contained in the instructions.

A2.2.7 Machinery (Regulation (EU) 2023/1230)[31]

Article 3 Definitions

(3) 'safety component' means a physical or digital component, including software, of a product within the scope of this Regulation, which is designed or intended to fulfil a safety function and which is independently placed on the market, the failure or malfunction of which endanger the safety of persons, but which is not necessary in order for that product to function or for which normal components may be substituted in order for that product to function;

(4) 'safety function' means a function that serves to fulfil a protective measure designed to eliminate, or, if that is not possible, to reduce, a risk, which, if it fails, could result in an increase of that risk;

(17) 'instructions for use' means the information, provided by the manufacturer when the machinery or related product is placed on the market or put into service, to inform the user of the machinery or related product, of the intended and proper use of that machinery or related product, as well as information on any precautions to be taken when using or installing the machinery or related product, including information on the safety aspects, and on how to keep that machinery or related product safe, and to ensure that it remains fit for purpose during its entire lifetime;

Article 10 Obligations of manufacturers

7. Manufacturers shall ensure that the machinery or related products are accompanied by the instructions for use and the information set out in Annex III. The instructions may be provided in a digital format. Such instructions and information shall clearly describe the product model to which they correspond.
When the instructions for use are provided in digital format, the manufacturer shall:
(a) mark on the machinery or related product, or, where that is not possible, on its packaging or in an accompanying document, how to access the digital instructions;
(b) present them in a format that makes it possible for the user to print and download the instructions for use and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the machinery or related product; this requirement also applies where the instructions for use are embedded in the software of the machinery or related product;
(c) make them accessible online during the expected lifetime of the machinery or related product and for at least 10 years after the placing on the market of the machinery or related product.
However, at the request of the user at the time of the purchase, the manufacturer shall provide the instructions for use in paper format free of charge within one month.
In the case of machinery or a related product intended for non-professional users or that can, under reasonably foreseeable conditions, be used by non-professional users, even if not intended for them, the manufacturer shall provide, in paper format, the safety information that is essential for putting the machinery or related product into service and for using it in a safe way.

[31] Consolidated text: Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02023R1230-20230629

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The instructions for use, the safety information and the information set out in Annex III shall be in a language which can be easily understood by users, as determined by the Member State concerned, and shall be clear, understandable and legible.

Annex III
1.7.4 Instructions for use

In addition to the obligations set out in Article 10(7), instructions for use shall be drawn up as set out below.
By way of exception to Article 10(7), the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or its authorised representative may be supplied in only one official language of the Union which the specialised personnel understand.
1.7.4.1. General principles for the drafting of instructions for use
(a) The contents of the instructions for use shall cover not only the intended use of the machinery or related product but also take into account any reasonably foreseeable misuse thereof;
(b) In the case of machinery or related products intended for use by non-professional operators, the wording and layout of the instructions for use shall take into account the level of general education and acumen that can reasonably be expected from such operators.
1.7.4.2. Contents of the instructions for use
1. Instructions for use shall contain, where applicable, at least the following information:
(a) the business name and full address of the manufacturer and, where applicable, of its authorised representative;
(b) the designation of the machinery or related product as marked on the machinery or related product itself, except for the serial number (see section 1.7.3);
(c) the EU declaration of conformity, or the internet address or machine readable code, where the EU declaration of conformity can be accessed, in accordance with Article 10(8);
(d) a general description of the machinery or related product;
(e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery or related product and for checking its correct functioning;
(f) a description of the workstation(s) likely to be occupied by operators;
(g) a description of the intended use of the machinery or related product;
(h) warnings concerning the ways in which the machinery or related product must not be used that experience has shown might occur;
(i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery or related product is to be mounted;
(j) instructions relating to installation and assembly for reducing noise or vibration;
(k) instructions for the putting into service and use of the machinery or related product and, if necessary, instructions for the training of operators;
(l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;
(m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;
(n) the essential characteristics of tools, which may be fitted to the machinery or related product;
(o) the conditions in which the machinery or related product meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;
(p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery or related product and of its various parts where these are regularly to be transported separately;
(q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;

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(r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed taking account of the design and the use of the machinery or related product;
(s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;
(t) the specifications of the spare parts to be used, when these affect the health and safety of operators;
(u) the following information on airborne noise emissions:

- *(i) the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB (A); where this level does not exceed 70 dB (A), this fact shall be indicated;*
- *(ii) the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 μPa);*
- *(iii) the A-weighted sound power level emitted by the machinery or related product, where the A-weighted emission sound pressure level at workstations exceeds 80 dB (A).*

These values shall be either those actually measured for the machinery or related product in question or those established on the basis of measurements taken for technically comparable machinery or for a technically comparable related product, which is representative of the machinery or related product to be produced.
In the case of very large machinery or a related product, instead of the A-weighted sound power level, the A- weighted emission sound pressure levels at specified positions around the machinery or related product may be indicated.
Where the harmonised standards or common specifications adopted by the Commission in accordance with Article 20(3) cannot be applied, sound levels shall be measured using the most appropriate method for the machinery or related product.
Whenever sound emission values are indicated, the uncertainties surrounding these values shall be specified. The operating conditions of the machinery or related product during measurement and the measuring methods used shall be described.
Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels shall be measured at a distance of 1 m from the surface of the machinery or related product and at a height of 1,6 m from the floor or access platform. The position and value of the maximum sound pressure shall be indicated.
With respect to noise reduction machinery or related products, the instructions for use shall specify, where appropriate, how to correctly assemble and install that equipment (see also section 1.7.4.2(1), point (j)).
Where specific Union legal acts lay down other requirements for the measurement of sound pressure levels or sound power levels, those legal acts shall be applied and the corresponding provisions of this section shall not apply;
(v) information on the necessary precautions, devices and means for the immediate and gentle rescue of persons;
(w) where machinery or related products are likely to emit non- ionising radiation, which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons;
(x) where the design of machinery or related products allows emissions of hazardous substances from the machinery or related product, the characteristics of the capturing, filtration or discharge device if such device is not provided with the machinery or related product, and any of the following:

- *(i) the flow rate for the emission of hazardous materials and substances from the machinery or related product;*
- *(ii) the concentration of hazardous materials or substances around the machinery or related product coming from the machinery or related product or from materials or substances used with the machinery or related product;*
- *(iii) the effectiveness of the capturing or filtration device and the conditions to be observed to maintain its effectiveness over time.*

The values referred to in the first subparagraph shall either be actually measured for the machinery or related product in question or established based on measurements in respect of technically comparable machinery or a technically comparable related product, which is representative of the state of the art.

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A2.2.8 Equipment and protective systems intended for use in potentially explosive atmospheres – ATEX (Directive 2014/34/EU)[32]

Article 6 Obligations of Manufacturer

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

Annex II

1.0.6. Instructions

(a) All equipment and protective systems must be accompanied by instructions, including at least the following particulars:

- *a recapitulation of the information with which the equipment or protective system is marked, except for the batch or serial number (see point 1.0.5), together with any appropriate additional information to facilitate maintenance (e.g. address of the repairer, etc.);*
- *instructions for safe:*
  - *putting into service,*
  - *use,*
  - *assembling and dismantling,*
  - *maintenance (servicing and emergency repair),*
  - *installation,*
  - *adjustment;*
- *where necessary, an indication of the danger areas in front of pressure-relief devices;*
- *where necessary, training instructions;*
- *details which allow a decision to be taken beyond any doubt as to whether an item of equipment in a specific category or a protective system can be used safely in the intended area under the expected operating conditions;*
- *electrical and pressure parameters, maximum surface temperatures and other limit values;*
- *where necessary, special conditions of use, including particulars of possible misuse which experience has shown might occur;*
- *where necessary, the essential characteristics of tools which may be fitted to the equipment or protective system.*

(b) The instructions must contain the drawings and diagrams necessary for the putting into service, maintenance, inspection, checking of correct operation and, where appropriate, repair of the equipment or protective system, together with all useful instructions, in particular with regard to safety.

(c) Literature describing the equipment or protective system must not contradict the instructions with regard to safety aspects

[32] Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014L0034&qid=1707751886095

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