



# whitepaper

## 2/2023

### New Machinery Regulation (EU) 2023/1230

Instructions for Use and Technical Documentation

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## Executive Summary

**The Machinery Regulation (EU) 2023/1230, applicable as of January 2027, changes some of the requirements for instructions to be provided by manufacturers of machinery and related products. Above all, it allows provision of instructions for use in digital format if these can also be downloaded during the machinery's entire lifetime and can be saved and printed. However, some details regarding these key requirements remain to be settled, e.g., the suitability of digital formats, the way access shall be provided for download (Will it be allowed to require input of a password, for instance?), the versions to be provided in the case of series manufactured machinery, and the extent to which instructions embedded in a machine's software will have to be printable.**

One of the limitations imposed on providing the instructions in digital format even appears impractical. The requirement to supply a printed version within one month of purchase if the user requests it (especially in case of partly completed machinery) is not realistic as the manufacturing process can often begin only after the purchase order has been placed

and takes many months. In many cases of custom-made machinery, the instructions for use can only be drafted at a late stage in the design and manufacturing process.

Providing instructions for use and safety information in print remains required if the machinery can be considered "*machinery for non-professional users*". The meaning of the latter term may be debated, while the requirement itself appears somewhat anachronistic in this digital age. Also, the respective wording used in the regulation lacks clarity and is thus open to interpretation. Clarifications, provided in a yet to be drawn up Guide by the EU Commission, are urgently needed, so economic operators can prepare in time to meet the new requirements.

The definition of the term "*instructions for use*" now includes an indirect requirement to provide information on how the user can ensure that the machinery does not only remain safe but also "*fit for purpose during its entire lifetime*". tekem Europe understands this to refer to the right to repair machinery and thus to suitable information on how to do it. In the interest of sustainability, we welcome this extension. However, the industry will need further guidance regarding the practical implications and the limits of this requirement, particularly regarding the meaning of the term "*lifetime*".

With this Whitepaper, tekem Europe wants to clarify, point out unclear points, and propose solutions to support the drafting of the Guide to the Machinery Regulation.

### CONTENT

Introduction.....	3
Requirements of the Articles.....	5
Article 3, Definitions.....	6
Article 10, no. 7, 1 <sup>st</sup> paragraph, 1 <sup>st</sup> sentence.....	10
Article 10, no. 7, 1 <sup>st</sup> paragraph, 2 <sup>nd</sup> and 3 <sup>rd</sup> sentence .....	12
Article 10, no. 7, 2 <sup>nd</sup> paragraph, (a) .....	14
Article 10, no. 7, 2 <sup>nd</sup> paragraph (b) .....	15
Article 10, no. 7, 2 <sup>nd</sup> paragraph, (c).....	18
Article 10, no. 7, 3 <sup>rd</sup> paragraph.....	19
Article 10, no. 7, 4 <sup>th</sup> paragraph .....	21
Article 10, no. 7, 5 <sup>th</sup> paragraph.....	23
Article 10, no. 8 .....	24
Requirements of Annex III .....	27
Technical documentation (technical file), Annex IV .....	28
Authors.....	32
Imprint .....	34

## Introduction

The European Association for Technical Communication – tekomp Europe e.V. (tekomp Europe) welcomes the Machinery Regulation (EU) 2023/1230; herein MR, which will succeed the Machinery Directive 2006/42/EC (herein MD) as of January 20, 2027.

The new law will have a great impact on Technical Communication as with the new law the EU did open the door to digital instructions for use. Between EUR 6.63 billion and EUR 26.5 billion are spent every year by approx. 82.239 companies for printing instructions for use for machinery. The acceptance of printed instructions for use is questionable, as 62.7% of all users don't want paper as format for the instructions for use. It is expected that by the introduction of digital instructions for use printing costs can be reduced significantly and that digital instructions for use will contribute substantially to environmental friendliness.

Besides allowing supply of digital instructions for use, the MR contains improvements of rules and regulations, aligning it with the New Legislative Framework (NLF).

tekomp Europe participated in the legislative process. It should be acknowledged that the wording of the MR is a compromise between the respective stakeholders. Consequently, the wording may be considered as lacking optimum precision and clarity. tekomp Europe would like to address open issues and sections to improve the understanding of the MR in the further discussion process. In the meantime, technical communicators will have to manage and deal with the different issues in this state of uncertainty and doubts regarding the exact interpretation.



As has been practiced for the MD, the application of the rules and regulations will be significantly influenced by the yet to be developed European Commission's Guide to the application of Machinery Regulation, which will provide background information and statements forming the basis for the interpretation of the MR. It is expected that the guidance document will be published by the European Commission before the MR applies.<sup>1</sup> Certainly, the guidance document will give rise to a revision of the present whitepaper as well. This whitepaper aims to support technical communicators regarding the most crucial aspects of the MR adoption and application.

Furthermore, it is expected, that we will have EU Legislation dealing with digitalization (AI, cyber resilience) and the Green Deal shortly. Such legislation may have some impact on machinery and consequently on the application of the MR as well. tekomp Europe will follow the developments continuously and analyze the impact in detail.

Finally, tekomp Europe would like to emphasize the need for a discussion within the community of technical communication dealing with the impact of the MR and encourages the reader to participate in that discussion. Please use the following contact data for any contribution: European Association for Technical Communication – tekomp Europe e.V., Heilbronner Straße 86 70191 Stuttgart, GERMANY, +49 711 65704-0, info@tekomp.de, www.tekomp.eu



**Tiziana Sicilia, President tekomp Europe**

Stuttgart, November 1, 2023

<sup>1</sup> The Machinery Regulation (EU) 2023/1230 came into force 20 days after its publication on 29.06.2023, which is 19.07.2023. But it will have to be applied only as of 20.01.2027 (for details see Article 54 of the Regulation and the Corrigendum to Regulation (EU) 2023/1230 published in the OJ on 4.07.2023)

## Requirements of the Articles

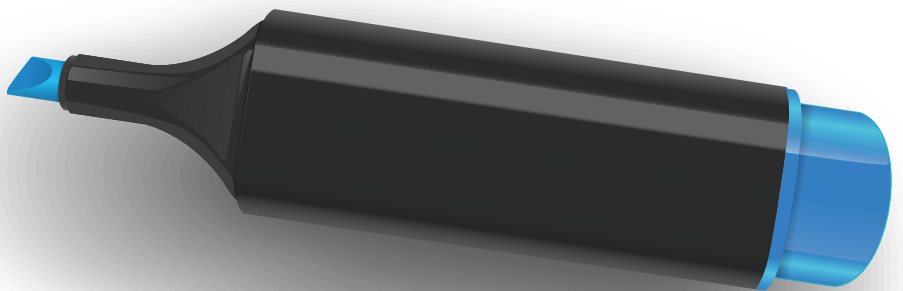
This Whitepaper explains the MR, following the different articles addressing the instructions for use as well as the technical documentation.

Besides the definitions, instructions for use are addressed within the set of obligations of manufacturers of machinery and partly completed machinery as well as importers or distributors of machinery and/or partly completed machinery. The set of regulations is as follows:



- **Article 3**    **Definitions**
- **Article 10**    **Obligations of manufacturers of machinery and related products**
- **Article 11**    **Obligations of manufacturers of partly completed machinery**
- **Article 13**    **Obligations of importers of machinery and related products**
- **Article 14**    **Obligations of importers of partly completed machinery**
- **Article 15**    **Obligations of distributors of machinery and related products**
- **Article 16**    **Obligations of distributors of partly completed machinery**

The obligations dealing with partly completed machinery as well as those dealing with the obligations of the importer, or the distributor are based on the obligations of the manufacturer of machinery; it can be stated that Article 10 is the “backbone” of obligations dealing with instructions for use. Consequently, the focus of the following comments is on Article 10.



## Article 3, Definitions

**(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;

**(18)** ‘manufacturer’ means any natural or legal person who:

- (a)** manufactures products within the scope of this Regulation or who has those products designed or manufactured, and markets those products under its name or trademark; or
- (b)** manufactures products within the scope of this Regulation, and puts those products into service for its own use;

[...]

**(34)** ‘lifetime’ means the period from the moment that machinery or a related product is placed on the market or put into service until the moment that it is discarded, including the effective time when the machinery or related product is capable of being used and the phases of transport, assembly, dismantling, disabling, scrapping or other physical or digital modifications foreseen by the manufacturer;

[...]

**(36)** ‘professional user’ means a natural person who uses or operates machinery or a related product in the course of his or her professional activity or work.

### Instructions for use

The definition provided in Article 3 first contains what has been expected and may be taken for granted regarding a definition of the term instructions for use. Taking a closer look, however, the second half of the sentence, which refers to the “*entire lifetime*” of the machinery is remarkable.

It should be noted that “*Instructions for use*” does not mean a document and certainly does not imply a defined name for a document. Rather, “*instructions for use*” means the sum of all information to be provided as defined and in accordance with the requirements of this regulation.

## Remaining fit for purpose during its entire lifetime

The MD and the MR are legislative acts dealing with placing machinery on the Union market<sup>2</sup>. With this concept in mind, it appears logical to assume that the responsibility of the machinery manufacturer will end after placing the machinery on the Union market, provided he also fulfills his obligation to provide the user with instructions for maintenance (which is also required by the MD).

The requirement to provide information which will ensure that the machinery can be kept “fit for purpose” for its entire lifetime extends the obligations of the manufacturer (or any other person responsible for the instructions for use) beyond the time of placing the machinery on the market. The reason for this extension of responsibility clearly is the idea of sustainability. Based on the “Green Deal”<sup>3</sup>, the EU is focused on having durable products in the Union market; products which can be maintained/serviced and repaired. Considering the long service life of most machinery, it can be quite a challenge to provide the user with all information needed to keep the machinery fit for its purpose.

**Imagably, such information will have to include more than instructions for “standard” maintenance but may also have to include information for repair.**

Also, the term “ensure” seems to imply that the information should be of a quality allowing users to take all necessary action on their own.

It will be challenging to define such requirements in greater detail, particularly with a view to the kind of information exactly required so that instructions for use comply with Article 3 subparagraph 17.

## Non-professional and professional user

The term “non-professional user” is not defined in the regulation. Only its obvious opposite “professional user” has been defined as “a natural person who uses or operates machinery or a related product in the course of his or her professional activity or work” (Article 3, subparagraph 36). Thus, “non-professional user” should be understood to mean a user who is using the product in some way, but not in a professional context. An attempt at a definition of “non-professional user” therefore might read “a natural person who uses or operates machinery or related products outside his or her professional activity or work”. Interestingly, Article 1 of the regulation, dealing with its subject matter, mentions “consumers and professional users” as the primary protection targets of the regulation. This appears to imply that non-professional users will primarily be consumers.

<sup>2</sup> Union market in this whitepaper refers to the European single market (also known as “European internal market” and “European common market”). It includes the Member States of the EU as well as Norway, Iceland, and the Principality of Liechtenstein.

<sup>3</sup> “Green Deal” here refers to two draft legislative acts of the EU, the Ecodesign regulation and the Right-to-Repair directive (see Proposal for a REGULATION establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC by EUROPEAN COMMISSION COM(2022) 142, and the Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on common rules promoting the repair of goods and amending Regulation (EU) 2017/2394, Directives (EU) 2019/771 and (EU) 2020/1828

It will be a challenge for manufacturers to assess whether the machinery will be used by a professional user or a non-professional user. Of course, the manufacturer may define who shall use the product – from the legal perspective of the MR, the defined “*reasonably foreseeable conditions*” of use are relevant. That is, if the manufacturer can anticipate use by non-professional users, the product design and the instructions for use should address this properly. If the reasonably foreseeable conditions of use cover both user types, the yet to be drafted EU’s guidance document should clarify the extent to which use by non-professional users will have an impact on the instructions.

**tekom Europe suggests the understanding that a minority of non-professional users should not be sufficient to classify the machinery as intended for “non-professional users”.**

## A non-professional user is not necessarily an unskilled user

Vice versa, professional users could not be sufficiently skilled or almost unskilled. Annex III requires manufacturers to provide information on the requirements regarding user qualification, see Annex III, 1.7.4.2 (k) “*if necessary, instructions for the training of operators;*”.

Instructions for use shall provide information on the intended use (see Annex III, 1.7.4.2 (g) ff and, if necessary, instructions for the training of operators (see Annex III, 1.7.4.2 (k). They will thus have to explain the safe use of the product. Professional users work in a regulated environment. This has consequences for the way instructions must be provided to them and on the content of these instructions (see occupational safety and health regulations based on the Treaty on the Functioning of the European Union, and in particular article 153 thereof). The respective employer will bear considerable responsibility for safe use by professional users. If the product is used by “*non-professional users*”, however, there will not be an employer ensuring safe use. Therefore, the wording and layout of instructions for use for non-professional users “*shall take into account the level of general education and acumen that can reasonably be expected from such operators*” (quoted from Annex III section 1.7.4.1 (b).

**If use by non-professional users is unwanted, it must be excluded by suitable measures, such as distribution instructions and paths as well as a clear statement to this effect in the instructions.**



## Obligations of the manufacturers of machinery

The obligations of the manufacturers of machinery regarding instructions for use are included in the set of obligations listed in Article 10. Article 10 looks familiar, as the same obligations have been implemented in all the regulations and directives based on the NLF. Thereby the instructions for use have been moved from a rather “secret and hidden place” in Annex I, chapter 1.7.4 MD to a more prominent place in the MR. This underlines the importance of the requirement for provision of instructions for use. Any non-compliance with the obligations listed in Article 10 will be deemed as formal non-compliance, which would allow the market surveillance authorities to initiate any action appropriate to remedy such formal non-compliance (see Article 46).



## Article 10, no. 7, 1<sup>st</sup> paragraph, 1<sup>st</sup> sentence

### Article 10

Obligations of manufacturers of machinery and related products

[...]

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.

### Manufacturer

Article 10 addresses the manufacturer. Spontaneously the term “*manufacturer*” is associated with “*placing the product on the market*”, which makes the machinery available to potential customers and means that it will be marketed.

However, one should keep in mind that the term “*manufacturer*” is used differently in the MR from everyday use. It includes a natural or legal person, who manufactures machinery for his own use and machinery substantially modified by the user for specific production purposes. Finally, it may also be applied to the making of related products such as equipment for clamping of parts and materials during assembly processes. The MR strictly regulates that identical rules apply to manufacturers marketing their machinery and for manufacturers producing machinery for their own use. The corresponding actions are considered “*placing on the market*” or “*putting into service*”.

**Therefore, the obligation to provide technical documentation and proper instructions for use also applies to machinery that is meant for the manufacturer’s own use.**

### Accompanied by instructions

The obligation to ensure the product is accompanied by instructions was first defined in the NLF and has been established in all regulations and directives based on the NLF. For years, it was not clear whether this requirement implies that the instructions must be provided in paper format. It turned out to be commonly accepted that paper format is required by the market surveillance authorities where the applicable EU regulation or directive requires instructions for use which “*accompany*” the product.

With the MR it is now clear that “*accompanied by instructions*” does equally mean digital instructions since the MR allows the provision of digital instructions for use and reducing the supply of printed instructions to a minimum or waiving at them completely under given prerequisites.

**It may be argued that the “new” understanding of “accompanied by the instructions for use” (which now also means instructions for use in digital format) can be viewed as a type of general statement that may also be applied to other NLF directives and regulations, which do not expressly allow digital formats, such as the directives dealing with low voltage appliances, measuring devices, or pressure equipment.**

## Instructions for use and Information

The term “**instructions for use**” refers to the definition in **Article 3, subparagraph 17.**

“**Information set out in Annex III**” refers to the following sections:

- 1.7.** with all its subsections for all types of machinery and related products
- 2.2.1.1.** and **2.2.2.2.** for portable hand-held or hand-guided machinery or related products
- 2.4.10.** for machinery or related products for plant protection products application
- 3.6.** with all its subsections for machinery or related products presenting risks due to their mobility
- 4.3.** and **4.4.** with all of their subsections for machinery or related products presenting risks due to lifting operations
- 6.5.** for machinery or related products presenting particular risks due to the lifting of persons

## Article 10, no. 7, 1<sup>st</sup> paragraph, 2<sup>nd</sup> and 3<sup>rd</sup> sentence

7. [...] The instructions may be provided in a digital format. Such instructions and information shall clearly describe the product model to which they correspond.

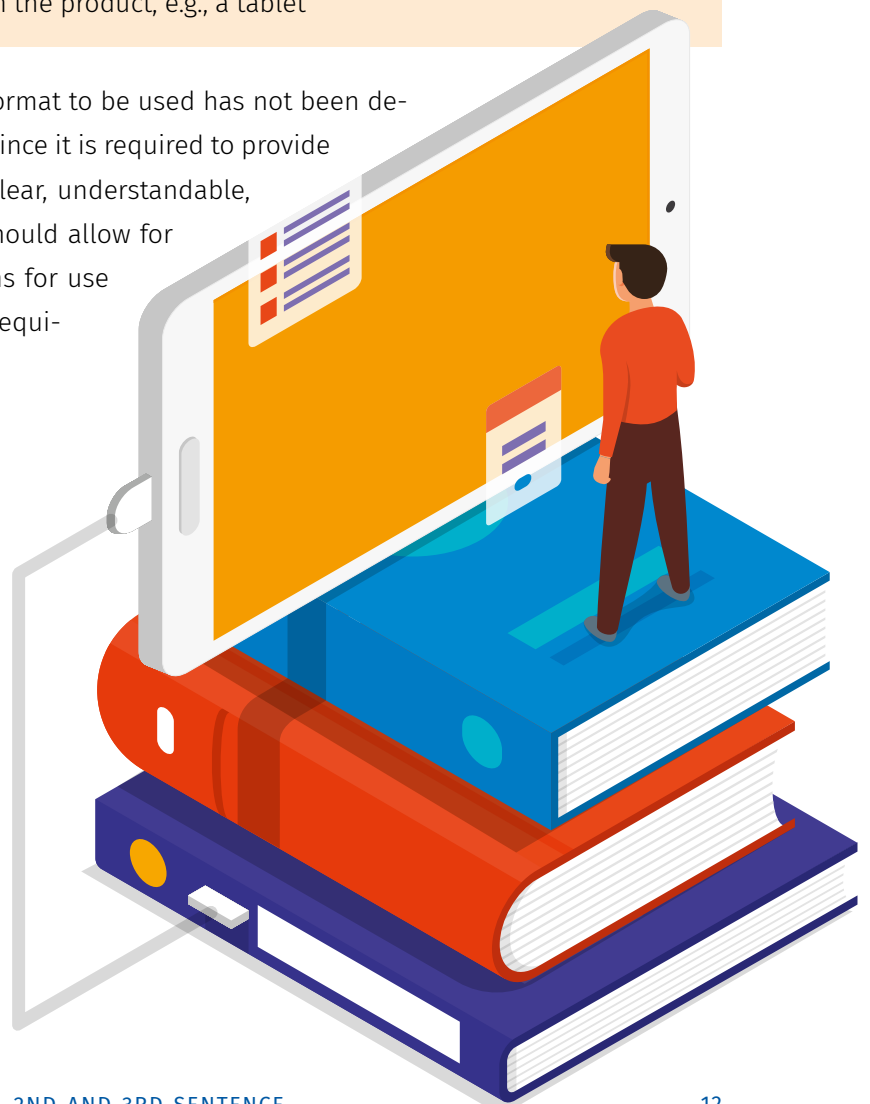
### Provided in a digital format

The short sentence which allows the manufacturer to “provide” the instructions in digital format gives room for interpretation, as the type of “digital format” is not defined. This is not surprising because the MR claims to be “neutral” regarding technology aspects – how the requirement is fulfilled shall remain at the discretion of the economic operators.

**“A provision in a digital format”** could be one or more of the following:

- Download from the internet
- Mass storage device delivered with the product
- Mass storage integrated into the product together with all means needed to display the instructions alongside the product
- Reading device delivered with the product, e.g., a tablet

Additionally, the type of digital format to be used has not been defined (HTML, PDF etc.). However, since it is required to provide instructions for use, which are clear, understandable, and legible, the digital format should allow for a presentation of the instructions for use which is compatible with these requirements.



Another requirement that must be kept in mind is that the digital format must allow creating a printed version of the instructions for use if requested by the user.

**It appears that printable instructions for use shall form a type of “baseline”, while non-printable digital formats (like video, for instance) may enrich or supplement the printable instructions.**

The printable “*baseline*” information also forms an essential part of the technical documentation (file) required in Annex IV, Part A (i) and Part B (i).

## Instructions for use

Only the instructions for use and the declaration of conformity or the declaration of incorporation of partly completed machinery, but no other information is mentioned with respect to the digital format. The background is that the possibility to provide information in digital format has only been discussed regarding the instructions for use during the legislative procedures.

The use of the terms “*instructions*” and “*such instructions and information*” apparently mean the same as „*instructions for use*” in the preceding sentence.

**It may be noted that the legislator is not concerned here with a specific related document, e.g., an instruction handbook, but rather with the content and information as such, which may be provided digitally.**

Consequently, it is evident that the legislator does not require a specific designation for a document to be provided. The manufacturer can choose suitable designations for the documents he supplies.

## Product model

The requirement to “*clearly describe the product model*” to which the information is referring is a matter of course and can also be found in IEC/IEEE 82079-1, clause 7.2 “*identifiers*”. The user must not accidentally access information that does not apply to the specific machinery or related product. Ensuring this is the responsibility of the manufacturer. In that sense “*Model*” could also apply to a specific product type, a product version etc.

## Article 10, no. 7, 2<sup>nd</sup> paragraph, (a)

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;

### Mark

“Mark on the machinery” should be understood to refer to a physical label. Care must be taken if a manufacturer plans to provide this mark by displaying it on a display integrated into the product because this would require that the user can operate the display and call up the mark without any digital instructions. (The need for this might result in a recursive access reference, which must be avoided.)

**It must be clear what the mark stands for. Some standards provide pictograms that may be used for this purpose, such as the pictogram M01 in ISO 7010 and the pictogram shown in IEC/IEEE 82079-1:2019, clause 7.3, Figure 2.**

### How to access digital instructions

Information on how to access digital instructions clearly depends on the medium which is used for the presentation of the digital information. A link or, even better, an ID-Link can be used for download.

It is important to keep in mind that the information on how to access the digital instructions should also be presented in a human readable form, for instance by adding a link that is not too complex, so that a user can type it correctly. Additionally, accessing the information should not be too complicated.

**If the Internet is used as the channel of providing digital instructions, the landing page should allow easy navigation to the instructions for use. The landing page also must be provided in the appropriate language, or the language must be selectable.**

The accompanying document mentioned in Article 10, no. 7 paragraph 2, (a) must be a printed document. It cannot be provided in digital format only, for it would hardly make sense to provide a link to digital information in a digital format.



## Article 10, no. 7, 2<sup>nd</sup> paragraph (b)

(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;

### Presentation

**The presentation of the instructions for use includes the following components:**

- the digital format of the file(s)
- the software needed to present the information
- the device needed to present the file(s), including all requirements which the device must meet
- the storage medium
- the device needed to read the storage medium, especially if the storage medium is a USB stick or a CD-ROM; in this case one needs to take into account that use of USB sticks is often restricted because of the risks, and that CD-ROM devices are not used widely anymore
- the need for an internet connection including a sufficient transmission rate and the availability of the server
- devices needed to interact with the presentation of the information, e.g., a pointing device, touch screen, smartphone, or tablet, etc.
- ...

Consequently, the entire route used to provide the information must be appropriate to present the instructions for use in a way that is compliant with Article 10.

**Generally, risk assessment should be performed to evaluate and reduce all the risks which could result from the user not having access to the instructions for use, as it is required to provide access “at all times”. See appropriate recommendations in the “Delivery of Information for Use in Electronic Form – eDoc”.**

## Printable

Digital instructions for use must be printable. This requirement sounds a bit inappropriate considering the allowance to provide the information in digital format. However, it turned out as being non-negotiable during the legislative process as a “*fall back*”-position meant to ensure the accessibility of instructions for use. Also, a printable format may be considered a type of “*baseline*” requirement, as the MR requires adding the instructions for use to the technical documentation (file) specified in Annex IV, too.

**According to the state of the art, printability is guaranteed when the PDF format is used.**

An open issue is the format of the print. One may assume that it should be A4. The US letter format may also be appropriate if the print area is limited to the width of A4. Larger formats are not appropriate because it cannot be generally assumed that users will have the means to print large formats. Smaller formats are possible in principle but could lead to undesirable waste of paper (for instance, if A6 is printed on A4 paper).

### The requirement to provide “printable” instructions for use excludes some formats from use

- Video (real, animation, screen cast, or any combination of these types, together with text, illustrations, and audio information)
- Audio
- Interactive models
- AR
- VR





**It is therefore clear that digital instructions for use cannot be presented by means of video or augmented reality alone. These and other non-printable media may, however, be used as additional deliverables to make use more comfortable.**

However, by themselves they are not appropriate when it comes to complying with the obligations set forth by the MR.

## Downloading and saving

Digital formats can generally be saved on electronic devices but in practice the requirement gives rise to some questions regarding the downloading process.

One question is which format would allow the users to download the instructions for use most easily. A downloading process using common software and a common browser should comply with the requirement. In contrast, a process using proprietary formats appears problematic, as it cannot be expected that the user would be able to proceed. If proprietary formats are used, the software needed for display must be provided together with the digital instructions for use. Also, the software should not need an installation process since it cannot be assumed that the user has the administration rights needed to install the software. (For further information see also ISO/IEC/IEEE 26514:2022. In clause 9.3 this standard deals with the selection of appropriate media and formats. And it describes the design of software presenting instructions for use.) Furthermore, the manufacturer may consider using a landing page for download, which is also used to provide sensitive information to which access restrictions apply and are implemented by the manufacturer, for instance, by requiring input of a password. This would result in a “barrier”. It may be difficult or almost impossible to achieve compatibility between the requirement for easy accessibility and availability for download on the one hand and a restriction of access on the other hand. In the near future, legal or normative specifications regarding the „Digital Product Passport“ will likely be published. These are expected to provide further clarification regarding these issues.

## Information embedded in the software of the machinery

The requirement to provide the instructions for use in a printable and storable format also applies to any information embedded in the software of the machinery, such as “online-help”. The design of “online-help” systems usually is not focused on providing the information in a printable format. The MR does not require, however, that each and every bit of information provided must be printable; only the instructions for use and the information required according to Annex III must be printable.

Many content management systems allow creating a handbook and extracting online help chunks from the same source based on rules configured. The respective portions of handbooks can also be enhanced with jump markers that can be referenced in the software to place and display page help, parameter information, and tooltips in the right locations. For more information on options regarding information embedded in software see also ISO/IEC/IEEE 26514:2022.

## Article 10, no. 7, 2<sup>nd</sup> paragraph, (c)

(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.

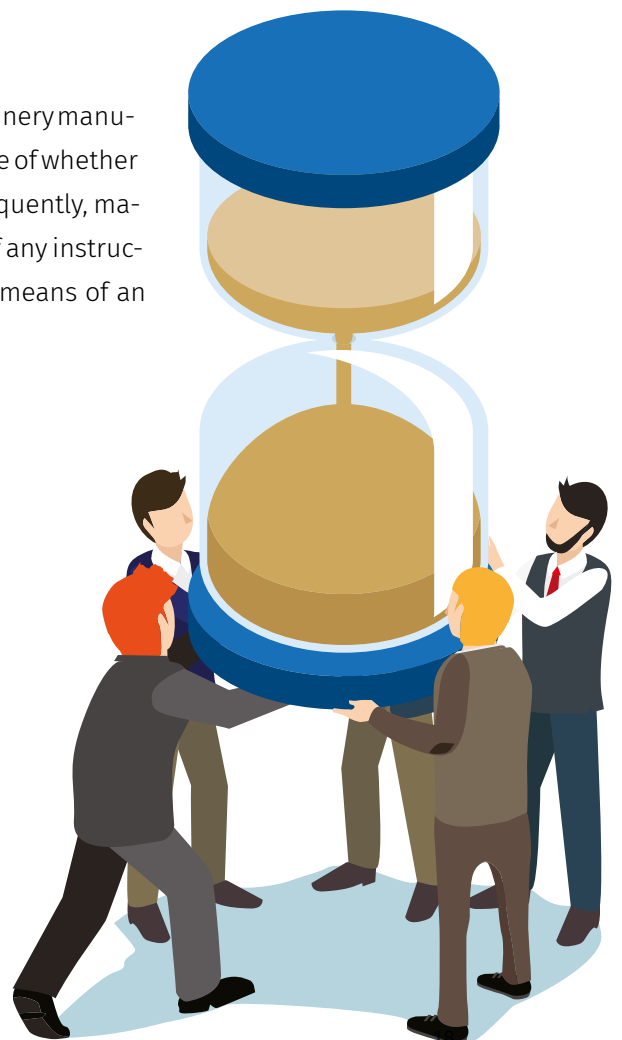
### Expected lifetime

A significant requirement dealing with accessibility of the instructions for use is the time frame during which the digital instructions for use must be accessible. It must be no less than the maximum time the manufacturer reasonably expects that the product is likely to be used – the expected lifetime.

Usually, the lifetime of machinery is a rather long time-period – 20 years are not totally unexpected. Manufacturers may find themselves in a kind of trap, as on one hand, the sales and the marketing departments often promote the machinery as long lasting, allowing use for “*generations*”. But on the other hand, manufacturers must ensure the accessibility for the entire period, bearing all the uncertainties in technical developments during that period. In future, manufacturers will have to assess carefully whether an excessive lifetime might lead to technical problems regarding the accessibility of the digital instructions for use.

### Accessible online

The requirement of accessibility is applicable to any machinery manufactured – including all kinds of variations and irrespective of whether the machinery is currently being marketed or not. Consequently, manufacturers will likely be forced to maintain a database of any instructions for use published and provide access to users by means of an “*online database*”.



## Article 10, no. 7, 3<sup>rd</sup> paragraph

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.

### Providing instructions for use in paper format

It appears anachronistic that manufacturers must provide digital instructions for use in a paper format if the user requests it. This requirement may be called into question but in the end, manufacturers will have to deal with it.

**tekem Europe would have preferred it to be up to manufacturers to decide based on their risk assessments whether printed instructions or use are needed on request, e.g., to ensure safety or usability. Instructions for use are a safety-related part of the machinery like any other physical safety-related part. Manufacturer are responsible for deciding on safety-related parts they use in their design. There is no reason why instructions for use should be dealt with in a different way.**

Manufacturers are required to organize a proper workflow for delivery of the instructions for use in paper format and they should include a delivery on demand option for printed instructions for use when designing their information landscape.

### Request of the user at the time of the purchase

The term “*time of the purchase*” addresses the day the user enters a purchase contract. It is irritating that the MR grants this right to “*the user*”, as the user clearly will not be the legal person entering into the purchase contract (in most cases it will be the user’s employer). It looks like the editors of the MR have not considered this but have just used the term “*user*” in accordance with all other rules and regulations.

**From the perspective of the manufacturer, it appears to be the most logical interpretation that the legal person, who purchases in his own name, shall have the right to request delivery of the instructions for use in paper format.**

## Within one month

Paper format shall be delivered within a fixed time frame of one month. This requirement does not appear to be compatible with the practice of the machinery industry, as the time gap between the purchase and manufacturing of the machinery is often significant and can span a few months or even years. Also, the instructions for use will often be drafted at the end of the manufacturing process and will be delivered as late as the time of the acceptance and takeover of the machine by the customer or even after assembly and installation of the machine have been completed.

**These facts give reason to state that this requirement cannot be fulfilled in every case of machinery purchase and should therefore be seriously reconsidered by the EU Commission.**

## Free of charge

The user is neither accountable for the cost of the paper format nor for transport of the printed instructions for use. The cost may range from a few Euros for postal services to the expense for delivery of several containers loaded with printed instructions for use.



## Article 10, no. 7, 4<sup>th</sup> paragraph

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.

The allowance of providing instructions for use in digital format is restricted as follows regarding machinery used by non-professional users:

### Intended for non-professional users

If the manufacturer intends to sell the machinery to non-professional users, the instructions for use cannot be provided as they would be to professional users. The decision of whether the restrictions set forth in Art. 10, no. 7, 4<sup>th</sup> paragraph, do apply does not only depend on the intentions of the manufacturer.

As is common in product safety law, the intentions may be overruled by the facts in the sense, that the reality of product use in the market regarding the user target audience may differ from the manufacturer's intention. This may give reason to state that the machinery is in fact machinery for non-professional users, although the manufacturer has designed it for professional users. This may be due to some sort of migration of the machinery from a professional to a non-professional user target audience.

If for example the machinery is marketed via online platforms, which are freely accessible to non-professional users, the manufacturer must acknowledge that he has aimed his machinery at non-professional users. However, facts indicating distribution to non-professional users will have to be of some significance; an individual, single instance, in which machinery is sold to a non-professional user, will most likely not be deemed as relevant.

**In similar cases, market surveillance authorities currently consider a product to be a “consumer product” when sales to consumers exceed 10% of the total quantity.**

## Safety information in paper format

Article 10, no. 7, 4<sup>th</sup> paragraph, allows some room for interpretation regarding the requirement to provide the “*safety information that is essential*” in paper format. The term “*safety information that is essential*” is not defined in the MR. It looks like the editors have reflected on footnote 114 in section 3.1 “*Manufacturer*” of the “*Blue Guide on the implementation of EU product rules 2022*” when using this term.<sup>4</sup>

From the perspective of technical writing, “*safety information*” could be construed to refer to the safety instructions and warning messages. However, one could also argue that safety information covers the entire instructions for use because it is the purpose of instructions for use to prevent hazard to users by providing information. Both ways of interpretation appear “*arguable*”. If technical writers follow the first, instructions for use in digital format are still allowed. If technical writers prefer the more restrictive interpretation, the instructions for use cannot be provided in digital format.

A third interpretation can be based on the exact phrasing of the requirement in Article 10, no. 7, 4<sup>th</sup> paragraph. It speaks of “*safety information that is essential for putting the machinery or related product into service and for using it in a safe way*”.

**The term “using” appears not to automatically refer to maintenance, repair, disposal, modification, etc. This interpretation allows for provision of printed instructions for use with reduced content, focusing on safe putting into service and use, while other information could still be provided in digital format.**

Considering the foregoing, the wording of Article 10, no. 7, 4<sup>th</sup> paragraph leaves the manufacturer with a lot of uncertainty and needs clarification urgently, such as could be provided by a guidance document for the MR.

**tekem Europe favors the third interpretation for the following reasons:**

- **The first interpretation does not make sense because consumers would not be able to use the product reasonably with such a printed document.**
- **The second interpretation undermines the EU’s sustainability goals.**
- **The third interpretation, however, assigns to the manufacturer the same responsibility for the instructions for use that he already has for the entire product. Therefore, this is consistent with the philosophy of the Regulation as a whole. It means that manufacturers can make a product-specific decision on the information to be printed, which considers both safety and sustainability.**

<sup>4</sup> Footnote 114 of the ‘Blue Guide’ on the implementation of EU product rules 2022 reads as follows: “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.”

## Article 10, no. 7, 5<sup>th</sup> paragraph

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.

### Language as determined by the Member State concerned

This requirement is using the wording suggested by the NLF. It may be debated, which language is actually intended because the requirement refers to a “*language which can easily be understood by the user*”. From the start of the NLF, it appears that this wording intends to refer to the Official Language (or Languages) of the EU Member States. This understanding is supported by several EU guidance documents (see ATEX 2014/34/EU Guidelines, §79; Low Voltage Directive 2014/35/EU Guidelines § 16 and § 19; The ‘Blue Guide’ on the implementation of EU product rules 2022, footnote 113 for section 3.1).

### Clear, understandable, legible

To require presentation of instructions for use in clear, understandable, and legible form is a matter of course. IEC/IEEE 82079-1:2019 (see clause 5) includes principles and explanations on how these requirements may be fulfilled and provides assistance regarding this.



## Article 10, no. 8

The MD, applicable until today, requires manufacturers to include the contents of the declaration of conformity in the instructions for use as well as to provide a separate copy of the declaration of conformity containing, where applicable, the serial number of the individual machine. In practice, most manufacturers have simply added a copy of the declaration of conformity to the instructions for use. Art. 10 no. 8 is simplifying this, as it will be sufficient according to the MR to provide an internet address or a machine-readable code at which the declaration of conformity can be accessed in the instructions for use and the information set out in Annex III.

### Obligations of the manufacturers of partly completed machinery

Article 11, no. 7 of the MR lists the obligations of manufacturers of partly completed machinery regarding provision of instructions. The wording is very similar to that of Article 10, no. 7. However, the term “*instructions for use*” is replaced by the term “*assembly instructions*”.

The content of assembly instructions is now defined in Annex XI; the requirements have been extended substantially, as not only information regarding the correct assembly of the partly completed machinery is required but also information regarding later intended use of the partly completed machinery once it has been integrated into the final the machinery, particularly.

Partly completed machinery is a product like any other and therefore requires comprehensive assembly instructions. The peculiarity is that assembly instructions for partly completed machinery are primarily addressed to manufacturers of machinery or assemblies of machinery and thus to engineers.

Depending on the complexity of the partly completed machinery and the scope of activities that end users of the completed machinery will have to perform with the partly completed machinery, the manufacturer of the partly completed machinery must provide information that enables the manufacturer of the complete machinery to provide suitable instructions for use to the end users.

**In this respect, the manufacturer of the partly completed machinery may have to consider end users as a target audience for certain activities.**



**The new requirements listed in Annex XI, no. 2, a) to n) are as follows:**

The assembly instructions shall contain relevant information to be used in the instructions of the machinery or other partly completed machinery or equipment, in which the partly completed machinery is to be assembled. Each assembly instruction shall contain, where applicable, at least the following information:

- (a) a general description of the partly completed machinery;
- (b) the drawings, diagrams, descriptions and explanations necessary for the incorporation into the final machinery, maintenance and repair of the partly completed machinery and for checking its correct functioning;
- (c) warnings concerning the ways in which the partly completed machinery must not be used that experience has shown might occur;
- (d) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the partly completed machinery is to be mounted;
- (e) information regarding noise or vibration which is likely to be reduced by the incorporation;
- (f) information about the essential health and safety requirements set out in Annex III which are applicable to the partly completed machinery;
- (g) the essential characteristics of tools which may be fitted to the partly completed machinery;
- (h) the conditions in which the partly completed machinery meets the requirement of stability, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;
- (i) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the partly completed machinery and of its various parts where these are regularly to be transported separately;
- (j) 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;
- (k) 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;
- (l) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;
- (m) the specifications of the spare parts to be used, when these affect the health and safety of operators;

(n) a clear description of the version of the assembly instructions which corresponds to the partly completed machinery model.

If the partly completed machinery is intended to be used in machinery covered by Annex III, chapters 2 to 6, the assembly instructions must also contain relevant information to be used in the instructions for use for these machinery.

**Annex XI, No. 3 adds the following:**

The assembly instructions for partly completed machinery shall contain the EU declaration of incorporation, or the internet address or machine readable code where the EU declaration of incorporation can be accessed.

## Obligations of Importers and Distributors

The importers and distributors are not responsible for the instructions for use or the technical documentation as such. Their responsibility is limited to ensuring that the manufacturer has fulfilled his obligations, and that the user is provided with the required information.

However, importers should bear in mind that they are the ones placing the product on the market of the EU. They will, therefore, in many cases have to ensure that the instructions for use and technical documentation are fit for the EU market. This may extend far beyond the languages offered and may include the content, format, etc. Importers are, therefore, well advised to carefully study the requirements for instructions for use set forth in the MR and determine (by means of the purchase contract) which party is to ensure meeting them. They should also have a check-up procedure for instructions for use of imported goods in place.

**Importers should bear in mind that the EU will hold the importer liable and not a manufacturer based outside the EU and is thus out of the reach of market surveillance authorities.**

## Requirements of Annex III



**The contents of Annex III regarding the instructions for use have been slightly revised and extended. The new/revised sections are 1.7.4.2, r), v), w) and x):**

- (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;
- (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

Indirectly, additional content is also required by ANNEX III, 1.1.2 dealing with the test of safety-related control functions. To allow users to test them as required, they will need a description of both the function itself and the test procedures.

Also ANNEX III, 1.1.9 dealing with corruption of the machinery (and its software, safety-related control systems, etc.) will require adding specific information to manuals.

Further sections that will likely result in additional information having to be included in instructions for use for large machinery that people can/or must enter are ANNEX III, 1.1.7 and 1.6.2, which deal with emergency exits and rescue equipment needed.

# Technical documentation (technical file), Annex IV

The technical file required in Annex VII of the MR and currently by the MD (Annex VII) is referred to as the “*technical documentation*” in Annex IV of the MR and outlines requirements for both machinery and partly completed machinery in greater detail. Annex IV also lists requirements regarding software (the source code must be included). It should be noted that, notwithstanding the change in terminology (from “*technical file*” in the MD to “*technical documentation*” in the MR) this Annex is not listing information and documents to be provided to the user of the machinery, but only information to be collected and held available for scrutiny by the market surveillance authorities.

In detail, the following is required:

## Part A

### Technical documentation for machinery and related products

The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the machinery or related product with the applicable essential health and safety requirements set out in Annex III.



**The technical documentation shall include at least the following elements:**

- (a) a complete description of the machinery or related product and of its intended use;
- (b) the documentation on risk assessment demonstrating the procedure carried out, including:
  - (i) a list of the essential health and safety requirements that are applicable to the machinery or related product;
  - (ii) the description of the protective measures implemented to meet each applicable essential health and safety requirement and, when appropriate, the indication of the residual risks associated with the machinery or related product;
- (c) design and manufacturing drawings and schemes of the machinery or related product and of its components, sub- assemblies and circuits;
- (d) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (c) and of the operation of the machinery or related product;

- (e) the references of the harmonised standards referred to in Article 20(1) or common specifications adopted by the Commission in accordance with Article 20(3) that have been applied for the design and manufacture of the machinery or related product. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts, which have been applied;
- (f) 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 meet each applicable essential health and safety requirement;
- (g) reports and/or results of the design calculations, tests, inspections and examinations carried out to verify the conformity of the machinery or related product with the applicable essential health and safety requirements;
- (h) a description of the means used by the manufacturer during the production of the machinery or related product to ensure the conformity of the machinery or related product produced with the design specifications;
- (i) a copy of the instructions for use and the information set out in section 1.7.4 of Annex III;
- (j) where appropriate, the EU declaration of incorporation for partly completed machinery set out in Annex V, Part B, and the assembly instructions set out in Annex XI;
- (k) where appropriate, copies of the EU declarations of conformity of machinery or related products as well as any product covered by other Union harmonisation legislation incorporated into the machinery or related product;
- (l) for machinery or related products produced in series, the internal measures that will be implemented to ensure that the machinery or related product remains in conformity with this Regulation;
- (m) the source code or programming logic of the safety related software to demonstrate the conformity of the machinery or related product with this Regulation further to a reasoned request from a competent national authority provided that is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III;
- (n) for sensor-fed, remotely-driven, or autonomous machinery or related products, if the safety related operations are controlled by sensor data, a description, where appropriate, of the general characteristics, capabilities and limitations of the system, data, development, testing and validation processes used;
- (o) the results of research and tests on components, fittings or the machinery or related product carried out by the manufacturer to determine whether by its design or construction it is capable of being assembled and put into service safely.

## Part B

### Technical documentation for partly completed machinery

The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the partly completed machinery with the relevant essential health and safety requirements set out in Annex III.

**The technical documentation shall include at least the following elements:**

- (a) a complete description of the partly completed machinery and of its intended function when incorporated into or assembled with machinery or other partly completed machinery or equipment;
- (b) the risk assessment documentation showing the procedure carried out, including:
  - (i) a list of the essential health and safety requirements which apply to the partly completed machinery;
  - (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks;
- (c) design and manufacturing drawings and schemes of the partly completed machinery and of its components, sub- assemblies and circuits;
- (d) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (c) and of the operation of the partly completed machinery;
- (e) the references of the harmonised standards referred to in Article 20(1) or common specifications adopted by the Commission in accordance with Article 20(3) that have been applied for the design and manufacture of the partly completed machinery. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts, which have been applied;
- (f) 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 meet each applicable essential health and safety requirement;
- (g) reports and/or results of the design calculations, tests, inspections and examinations carried out to verify the conformity of the partly completed machinery with the applicable essential health and safety requirements;
- (h) a description of the means used by the manufacturer during the production of the partly completed machinery to ensure the conformity of the partly completed machinery produced with the design specifications;

- (i) a copy of the assembly instructions for the partly completed machinery set out in Annex XI;
- (j) for partly completed machinery produced in series, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied;
- (k) the source code or programming logic of the safety related software upon a reasoned request from a competent national authority, provided that is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III;
- (l) for sensor-fed, remotely-driven, or autonomous partly completed machinery, if the safety related operations are controlled by sensor data, a description, where appropriate, of the general characteristics, capabilities and limitations of the system, data, development, testing and validation processes used;
- (m) the results of research and tests on components, fittings or the partly completed machinery carried out by the manufacturer to determine whether by its design or construction it is capable of being assembled and incorporated safely.

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## Briefly explained: The New Machinery Regulation

The Machinery Regulation (EU) 2023/1230, applicable as of January 2027, changes some of the requirements for instructions to be provided by manufacturers of machinery and related products.

Above all, it allows provision of instructions for use in digital format if these can also be downloaded during the machinery's entire lifetime and can be saved and printed. However, some details regarding these key requirements remain to be settled.