Introduction to medical device labeling, standards and symbols

An overview of labeling standards and their application in Europe and beyond

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Overview of medical device labeling

Let's define what we mean by labeling, also referred to as information supplied by the manufacturer in some jurisdictions. The U.S. Food and Drug Administration defines medical device labeling as the information related to the identification and use of a medical device or accessory, in whatever form provided, which allows the medical device or accessory to be used safely and effectively.

Labeling includes the information that may be on the device itself, as well as information on the packaging, the Instructions for Use (IFU), implant card and other package inserts. Depending on the jurisdiction and context, the labeling may also include the device's marketing materials. Subject to the rules in each jurisdiction, this information can be provided in various formats, including written/printed, auditory, visual or multimedia (e.g., website, USB stick or CD/DVD-ROM).

Manufacturers may find it difficult and expensive to develop medical device labeling in a global market that spans many languages, cultures and continents. In the European Union (EU) alone, there are over 20 official languages. However, the use of symbols and the adoption of electronic labeling (e-labeling), where possible, can help simplify product labeling while also providing sufficient information for users.

General Safety and Performance Requirements for medical device labeling

Device labeling is part of the General Safety and Performance Requirements (GSPRs) of the **Medical Devices Regulation (EU) 2017/745 (EU MDR)** and the **In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (EU IVDR)**. Each device must be accompanied by labeling that provides the information needed to use the device safely and effectively, taking into account the training and knowledge of the potential users. The device, the legal manufacturer and the Authorized Representative (AR) (if applicable) must be appropriately identified. This information may be provided on the device itself, its packaging and/or in the IFU. Where applicable, this information also needs to be made available and maintained on the manufacturer's website. The GSPRs in Annex I, Chapter III of both the EU MDR and the EU IVDR provide specific requirements for the content of product labeling.

As far as is practical and appropriate, the information required to safely use the device must be provided on the device itself and/or on the packaging for each unit and/or on the packaging of multiple devices.

According to the EU MDR and the EU IVDR, the IFU must be provided together with the device, with the exception of Class I and Class IIa devices that can be safely used without such instructions. These instructions may be provided in written/printed form or in electronic format in accordance with the **Commission Implementing Regulation (EU) 2021/2226**.

For the EU IVDR, an IFU may not be required or may be abbreviated in duly justified and exceptional cases in which the device can be used safely and as intended without such instructions. The IFU may be provided in electronic format if the device is for professional use only and not for near-patient testing.

Languages according to the EU MDR and EU IVDR

The EU MDR and EU IVDR provide legal provisions that allow Member States to determine labeling language requirements at a national level in EU MDR Article 10 (11) and EU IVDR Article 10 (10).

Under the former EU Medical Device Directives, the EU Member States also had the same latitude to determine the language acceptable in their territory; however, this information was fragmented and mostly available in languages other than English, and it was, therefore, difficult to compile and track. To assist manufacturers under the EU MDR and EU IVDR, in October 2023, the Medical Device Coordination Group (MDCG) asked members to provide information on their national language requirements. This has resulted in the publication of two tables on the European Commission's website in January 2024: **MDR - Language Requirements for Manufacturers and IVDR - National Language Requirements for Manufacturers**

The tables outline each member state's language requirements for the label/IFU, implant card, Declaration of Conformity, Field Safety Notice, documents for conformity assessment, and graphic user interface (GUI) and are a convenient resource for manufacturers in determining the language requirements applicable to their device, as well as associated costs. Of note for manufacturers of medical device software is that the GUI is generally viewed in the same light as the label/IFU and would need to conform to the same requirements as the label/IFU in most territories.

The language requirement tables span 31 countries, including the 27 EU Member States, along with the additional European Economic Area (EEA) members of Iceland, Liechtenstein and Norway, and Turkey, which is a candidate for membership in the EU and has a customs union agreement in place with the EU. Taking a conservative approach, this would mean that manufacturers who intend to market their devices across Europe would need to translate each article of accompanying information into at least 25 languages.

Given the costs associated with labeling translation, some Member States have defined conditions to allow for English-only labeling, particularly for professional-use devices where the safe use of the device is less likely to be compromised. The particular circumstances vary depending on each member state's national implementing regulations. Interestingly, France requires that even labeling for professional users be provided in French but makes allowances for the GUI to be provided in English where the intended user is a professional user and under certain circumstances. Regardless of any potential exceptions, Emergo by UL recommends that all labeling be translated into the member state's official language (including labeling for professional-use devices). The risk management and human factors engineering processes are important here: the manufacturer is responsible for confirming that all intended users of the device, whether laypeople or professionals, understand the purpose of and how to use their products. You may expose your company to legal liabilities if labeling is not properly understood because it is not provided in the local language.

Note: Under certain circumstances, derogations may be possible in some Member States (i.e., a manufacturer may approach the competent authority and request an exemption to the official language requirement). This, however, typically is a Herculean feat and can be quite a protracted process. Derogations also may only be granted on a temporary or case-by-case basis and thus may not be a feasible commercial strategy.

Benefits of symbols

Symbols quickly communicate a concept to the user in a way that, if used properly, can transcend language differences. The use of symbols is voluntary but strongly encouraged, as there are many benefits of the use of symbols for medical device users and manufacturers.

Using symbols in medical device labeling can:

Improve clarity

Symbols can convey information in a way that is more visible and clear to the user. This can facilitate user safety and help mitigate the manufacturer's risk. Symbols can be easier to read than translations (which can contain errors) and lead to fewer mistakes and happier customers.

Save space

Label space is extremely limited; lines of translated text occupy precious space and minimize readability. However, one symbol that depicts "For Single Use Only" takes up far less space than 20+ translations of the phrase. As a result of the saved space, packaging can be more attractive.

Conserve costs

Translating instructions, warnings and IFUs is time-consuming and expensive. Symbols allow manufacturers to communicate information in a way that has universal meaning without the need for costly translation.

Harmonized standards

Per Annex I, Chapter III of the EU MDR and EU IVDR, the information supplied by the manufacturer should take the form of internationally recognized symbols, where appropriate. These symbols "must conform to the harmonised standards or common specifications" (EU MDR Annex I, Chapter III (23.1h) and EU IVDR Annex I, Chapter III (20.1h)). Compliance with a European Norm (EN) Harmonised Standard published in the "Official Journal of the European Union" (OJEU) presumes conformity with the relevant GSPRs (EU MDR/EU IVDR, Article 8).

The EN ISO 15223-1 standard, *Medical Devices - Symbols to be Used with Information to be Supplied by the Manufacturer*, is harmonized in the EU for **medical devices** and **IVDs**. EN ISO 15223-1:2021 superseded EN ISO 15223-1:2016 and uses all the symbols valid under EN ISO 15223-1:2016, plus a number of additional symbols. ISO 20417:2021, *Medical Devices - Information to be Supplied by the Manufacturer*, replaced EN 1041:2008+A1:2013, which has now been withdrawn. It is expected that ISO 20417:2021 will also be harmonized under the EU MDR and EU IVDR. These standards have been implemented in order to achieve alignment with the EU MDR and EU IVDR, as well as to keep pace with a changing regulatory environment.

For IVDs, ISO 18113-1, -2, -3, -4 and -5, *In Vitro Diagnostic Medical Devices - Information Supplied by the Manufacturer (Labeling)*, apply and address requirements specific to IVD users. ISO 18113-1 establishes general principles and concepts; ISO 18113-2 and ISO 18113-3 outline requirements for IVD reagents and instruments, respectively, intended for professional use; ISO 18113-4 and ISO 18113-5 lay out requirements for IVD reagents and instruments, respectively, intended for self-testing. The ISO 18113 series represents a group standard and has precedence over ISO 20417 concerning labeling requirements for IVDs. This series of standards has also been updated to align it with the EU MDR and EU IVDR and is expected to be harmonized under the EU IVDR.

EN ISO 15223-1:2021 (4th Edition)

EN ISO 15223-1 is a horizontal standard that is specific to medical devices (including IVDs). The symbols in EN ISO 15223-1 have been selected and updated to convey some of the required information of Annex I, Chapter III of the EU MDR and EU IVDR. The fourth edition of the standard greatly increases the number of symbols recognized in the EU for medical devices and IVDs. Relative to the third edition of the standard, an additional 25 symbols have been included in this update; 20 have been validated as per ISO 15223-2, and five are symbols previously published in ISO 7000, ISO 7001 and IEC 60417, which are vertical standards that contain information on internationally recognized graphical symbols to be used on equipment and for public information.

For example, this symbol communicates the warning "Do Not Resterilize" with a circle that contains the text "2 STERILIZE" and a diagonal slash through it. Using this symbol to indicate not to resterilize negates the need to translate the warning into each of the official member state languages.

Symbols do more than mitigate risk and reduce cost; application of EN ISO 15223-1, which is an EN Harmonized Standard published in the OJEU, gives a presumption of conformity with the relevant GSPRs. There is an overwhelming benefit to using EN ISO 15223-1 symbols.

With the many languages required to market a medical device in the EU, it can be prudent to avoid text when possible. Before using symbols, however, manufacturers should conduct a risk assessment to determine whether it is, in fact, appropriate to use a particular symbol.

Practical notes about EN ISO 15223-1:2021

One of the features of EN ISO 15223-1 is the annexes that correlate the symbols in the standard to the explicit requirement of Annex I, Chapter III of the regulations that the particular symbol addresses. For example, the "Manufacturer" symbol in section 5.1.1 addresses EU MDR, Annex I, Chapter III 23.2(c) and EU IVDR, Annex I, Chapter III 20.2(c), which require the name of the manufacturer to be present on the label. The symbols in EN ISO 15223-1 can be used to help meet the requirements for information supplied with the device, necessitated under the EU regulations.

Finally, it is worth mentioning that the EN ISO 15223-1 symbols are not the only symbols that exist. A manufacturer can certainly develop its own symbols, particularly when there is specific information to convey that is not addressed in the standard. As per the EU MDR and EU IVDR, where no harmonized standard or common specifications (CS) exist, the symbols and colors shall be described in the documentation supplied with the device. It should be noted that the associated description will need to be translated into the language of all EU countries where the device is marketed. EN ISO 15223-1:2021 symbols may be used without additional description since this standard is harmonized in the EU and published in the OJEU. However, it is good practice and strongly recommended to include a complete list of all symbols used and associated descriptions in the accompanying documentation, typically the IFU.

Note: 25 additional symbols have been added to the fourth edition of ISO 15223-1. These symbols have been added to achieve alignment with the EU MDR and EU IVDR.

EN ISO 20417:2021 (1st edition)

EN ISO 20417 replaces EN 1041 and provides much-needed clarity around information to be supplied by manufacturers with their devices under the EU MDR and EU IVDR. Firstly, the scope of EN ISO 20417 is wider than its predecessor and applies to all medical device manufacturers, including IVD manufacturers. It aligns with both the EU MDR and EU IVDR, specifying requirements for key aspects of the regulations, such as Unique Device Identification (UDI).

At over 80 pages long, EN ISO 20417 comprises a significantly higher number of requirements than EN 1041 (which spanned a mere 20 pages). Within the scope of the standard, it is clarified that it applies to accompanying documentation in varying formats and that this information includes both the label and other information. This is important clarification as the terms “label” and “labeling” are used interchangeably throughout the regulation, and the term “labeling” is not formally defined.

Acknowledging the role of e-labeling, which aligns with the EU MDR and EU IVDR acceptance of the use of digital formats for certain information and under particular circumstances, the standard also has a formal definition of e-documentation (3.6). Requirements for e-documentation are stated explicitly within the body of the standard. This compares to the term “alternate labeling,” which was employed in the EN 1041 standard but only addressed in Annex B of that standard. E-documentation is discussed further below.

In addition to alignment with the EU MDR and EU IVDR, EN ISO 20417 also facilitates global harmonization, since it is in alignment with the International Medical Device Regulators Forum (IMDRF) labeling guidelines, **IMDRF/GRRP WG/N47:2018** and **IMDRF/GRRP WG/N52:2019**. Annex D and Annex E of the standard include cross-references that outline how the requirements in the standard compare with the requirements in the IMDRF guidance documents.

ISO 18113:2022 series (2nd edition)

The second edition of the ISO 18113 group of standards has been revised to align with current regulations and requirements, most notably the EU IVDR. These standards are not yet harmonized under the EU IVDR but are considered state-of-the-art concerning IVD labeling.

The standards do not cover language requirements, as this falls under the domain of the regulations and national laws. Additionally, the standard does not apply to IVD medical devices for performance evaluation, shipping documents, material safety data sheets or marketing information.

The standard is organized into five parts, each part addressing a different aspect of labeling for IVD products; parts 1, 2 and 4 apply to IVD reagents, while parts 1, 3 and 5 apply to IVD instruments. Key updates reflected across the series in the second edition include references to UDI and associated requirements; annex ZA of each standard cross-references the requirements in the standard to the applicable GSPR in the EU IVDR; and updated terms and definitions. These updates align the standards with updated regulations and technological advancements.

ISO 18113 provides a comprehensive framework to confirm that all necessary and relevant information is provided to the users of IVD products, whether they are healthcare professionals or individuals conducting self-testing. It is, therefore, important that manufacturers comply with these requirements to facilitate correct product use.

Note: For IVDs, the ISO 18113 series of standards takes precedence over ISO 20417.

Symbols index

Examples for major categories of EN ISO 15223-1 symbols are provided below, along with a description. For the full list of symbols, the standard must be purchased from a National Standards Body.

Manufacturing symbols

Manufacturing symbols are used to convey information about the manufacture of a product. Information such as by whom, when and where it was made, as well as product identification data, fall within this category.

Indicates the Device Manufacturer

Includes name and address of the manufacturer

Authorized Representative in the European Community

Includes the name and address of the AR

Batch Code

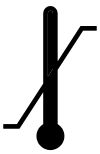
Indicates the manufacturer's batch code so the batch or lot can be identified

Catalogue Number

Indicates the manufacturer's catalogue number so the device can be identified

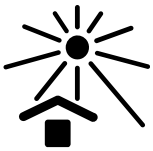
Storage symbols

Many medical devices have special considerations when it comes to storage. Factors such as temperature, exposure and humidity can affect the device's safety and performance.



Temperature Limit

Upper and lower limit temperatures shown next to horizontal lines

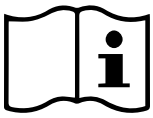


Keep Away from Sunlight

Indicates a device that needs protection from light sources

Safe use symbols

Risks associated with medical devices need to be identified and communicated to users to mitigate as far as possible hazardous situations arising from these risks. Safe use symbols act as a warning to convey and reduce some of that risk.



Consult Instructions for Use

Indicates the need for the user to consult the IFU

Do Not Reuse

Indicates a device that is intended for one use, or for use on a single patient during a single procedure

Contains Natural Rubber Latex

Warns those with allergies to certain proteins in latex

Caution

Indicates the need to consult the IFU for important cautionary information

Sterility symbols

Sterility symbols communicate important information about the sterile conditions of the product. This could mean how they were sterilized or warnings about conditional use.

Sterile

Indicates a device that has been subjected to a sterilization process

Do Not Resterilize

Indicates a device that is not to be resterilized

IVD symbols

IVD symbols are specifically used on IVD devices and communicate information germane to those product types.

In Vitro Diagnostic Medical Device

Should only be used to identify IVDs and note that the device is for “in vitro use”

Control

Indicates a control material that is intended to verify the performance characteristics of another medical device

Growth of e-documentation

E-documentation is defined as "any form of electronically accessible information supplied by the manufacturer related to a medical device or accessory," e.g., CD-/DVD ROM, USB stick, website (EN 20417:2021).

The EU now has 27 member countries, along with the EEA members of Iceland, Liechtenstein and Norway, driving the need for larger IFUs and accommodating more languages on limited packaging space. The primary reasons for e-labeling, aside from cost savings, are: (1) it facilitates fast and easy communication to the user of the most up-to-date information, potentially improving safety; and (2) it can reduce the environmental burden. Website IFUs and CD-ROMs also allow the manufacturer to demonstrate how their device is used in a way that static photos or illustrations cannot convey. A picture may be worth a thousand words, but a video is worth a thousand pictures!

Both the EU MDR and EU IVDR acknowledge and clarify the use of e-documentation. This reflects the ongoing digital transformation in healthcare and the need for more agile, transparent, and efficient regulatory compliance mechanisms.

Implementing Regulation 2021/2226, which replaced EU Regulation 207/2012, clarifies when electronic IFUs (e-IFUs) may be implemented. This regulation has specifically been implemented to support the EU MDR and outlines specific medical devices and accessories intended to be used under specific conditions which may have their IFUs provided in electronic form. These devices include: implantable and active implantable medical devices and their accessories; fixed installed medical devices and their accessories; and medical devices and their accessories with a built-in system visually displaying the IFU. These devices may employ e-IFUs only where they are intended for professional users and use by other persons is not reasonably foreseeable. The regulation also explicitly allows for medical device software to employ e-IFUs where they are provided by means of the software itself. This is a broadening of scope from the preceding regulation; as for software only, this is not limited to professional users e.g., includes medical app software for use by patients. Some organizations believe that in order to facilitate a level playing field, the scope of the regulation needs to be broadened even further, and in February 2024, these organizations came together to issue a **joint statement supporting the expansion of the use of e-IFUs in the medical devices sector**.

For manufacturers providing the IFU in electronic format, the regulation still mandates that a paper copy must be made available within seven days, if requested, at no additional cost to the user.

It should also be noted that the provision of the IFU in electronic form instead of in paper form should always be addressed via the manufacturer's risk management process; minimum requirements pertaining to a risk assessment for e-IFUs are outlined in Article 4 of the regulation. Additionally, if a device requires Notified Body involvement, the Notified Body must review for compliance with this regulation; therefore, manufacturers must keep on file documentation that supports compliance with the regulation.

Other key updates to the regulation are:

- Implant cards may be provided in electronic form
- Two additional elements must be taken into account when performing the required risk assessment (Art. 4): (1) the assessment of the e-IFU's compatibility with different devices that could be used to display the instructions, and (2) the management of different versions of the e-IFU, where applicable
- The information on how to access the IFU in electronic form shall also contain the Basic UDI-DI and/or the UDI-DI of the device (Art. 6)
- The website containing the e-IFU shall be protected against unauthorized access and tampering of content, and shall fulfill the requirements of Regulation (EU) 2016/679 (EU GDPR) (Art. 7)

When IFUs are to be provided in electronic format, the "Consult Instructions for Use" symbol (5.4.3, EN ISO 15223-1:2021) is an appropriate symbol to use on the label with an e-IFU indicator; this could be the URL for the IFU website. Annex A, section A.16 of the EN ISO 15223-1:2021 standard includes examples of the e-IFU indicator placement.

Under the IVDR (Annex I, Chapter III), e-IFUs can be provided for IVDs intended for professional use only, except for when the device is intended for near-patient testing.

Medical device software and labeling

Medical device software (MDSW) and the role it plays in healthcare applications has grown exponentially over the last few years. Due to its non-physical nature, it can be difficult to recognize how labeling, in particular, can be applied to MDSW. To be very clear, the same labeling requirements apply to MDSW as they do to traditional medical devices. Software labeling must be clear and visible to the user and must meet the requirements outlined in Annex I, Chapter III, GSPR 23. Where information is required on the "label," this information will typically be provided on the splash screen or "About" screen. This screen should also include a web address or other information on where the user can easily access the IFU and any other relevant accompanying information. The symbols outlined in EN ISO 15223-1:2021 apply to MDSW and should be used to convey information; for example, the "LOT" symbol may be used to communicate the version number of the software.

In alignment with the EU MDR and EU IVDR, some features unique to MDSW that will need to be considered for inclusion in accompanying documentation include, amongst others:

- Software version
- Cybersecurity implementation, residual risks and management
- Software updates and patches
- Information on any limitations of the software; compatible hardware, operating systems and any specific configurations or settings required
- For AI- and ML-enabled devices, information on what aspects and how the AI provides human oversight or control and what aspects and how the AI changes

As MDSW and its scope of application continue to evolve, the regulatory landscape will adapt to keep pace with evolution and ensure these technologies are safe and effective. Manufacturers will need to keep apprised of regulatory changes and best practices in labeling to support compliance and the safe and effective use of their products.

Medical device labeling best practices

1. **Safety is the first priority in implementing appropriate labeling.**
While reducing the cost of translations and printing is a benefit of using symbols or e-labeling, it should not be the primary concern. Medical device manufacturers have a regulatory and ethical responsibility to support the safe use of their products.

2. **Labeling must always comply with relevant regulations and standards in the target market.**
In the EU, application of the CE marking is viewed as confirmation of conformity.

3. **Readability**
Manufacturers should use clear, straightforward, unambiguous language that is easily understood by the intended users.

4. **Usability**
It is very important to examine what could happen if a user does not understand what the labeling means, or does not have proper access to the IFU as part of the risk analysis. Is there a risk of injury or even death? Are there disabilities, user preferences and needs that need to be accommodated? If so, provide more information instead of less, which may mean providing contextual explanations instead of simply using symbols. On the other hand, symbols may provide greater visibility and enhanced understanding for some information, in which case the use of symbols would reduce the risk associated with the device and its labeling. This is ultimately for the manufacturer to determine and justify.

5. **Accessibility**
As for e-IFUs and other accompanying documentation supplied in electronic format, paper instructions may add to the safety and convenient use of your device for the user. The decision regarding whether to use e-documentation must be examined from a risk management perspective.

6. **Multilingual translations**
If e-documentation is used, translated versions of the current revision must be readily available in hard copy, if requested.

7. **Software version control and updates**
The software version must be clearly indicated. Clear instructions must be provided on how users can verify the version they are using and how to obtain and install updates.

8. **Recordkeeping**
All versions of the e-IFU must be maintained and available on the website.

Learn more

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