LANGUAGE TRANSLATION
REQUIREMENTS OF MEDICAL DEVICE REGULATION (MDR)

Milestone Localization

BY
MILESTONE LOCALIZATION

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INTRODUCTION

The new **European Medical Device Regulation (EU MDR)** demands that manufacturers of medical devices abide by its stricter rules and regulatory requirements. This new regulation has placed significant importance on specific language requirements that must be adhered to.

We have collated this informational guide to equip you with essential information about the **language requirements** as outlined in the EU MDR.

It provides an overview of the **translation requirements** and challenges presented by the new regulations and how **language service providers** can help manufacturers streamline their translation efforts.

Please note that the EU MDR is a complex and continuously evolving regulation, and it's essential to refer to the official European Union websites or consult legal experts for the most up-to-date and comprehensive information on the regulation.

ABOUT EU MEDICAL DEVICE REGULATION

Officially published on **5th May 2017**, The new **European Medical Device Regulation(EU)** 2017/745 took effect on **25th May 2017**, replacing both the Medical Device Directive (93/42/EEC) and the EU's Directive on The Active Implantable Medical Devices (90/385/EEC).

However, it is vital to note that the EU MDR is an **evolving framework**, subject to continuous updates and changes to adapt to new advancements and guarantee the highest safety standards.

EU MDR intends to ensure **high safety** and **quality standards** for medical devices manufactured or supplied in the EU member states.

It defines all the prerequisites a manufacturer must comply with in order to sell medical devices in the European Union.

What constitutes a medical device under MDR?

As per the **EU MDR**, a medical device is “any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings”.

With the new MDR in place, there are a lot of devices that fall into the category of medical devices. It encompasses an array of items ranging from bandages and splints to diagnostic tools, surgical instruments, hospital beds, self-testing and monitoring devices and more.

Additionally, it also includes cosmetic devices such as non-prescription coloured contact lenses, dermal fillers and equipment used for cosmetic procedures like liposuction.

UPDATED MDR TIMELINES

The EU MDR came into force in 2017 with a **three-year** transition period which was extended due to the impact of the pandemic.

The most recent deadline extension took place in March 2023 when The European Council approved lengthening the transition period for medical devices under MDR regulation. Here are the updated transition deadlines:

26 MAY 2026
Class III custom-made implantable devices

31 DECEMBER 2027
Class III and **IIB** implantable devices

31 DECEMBER 2028
Class IIB non-implantable devices, **Class IIA** devices, and **Class I** sterile devices or **Class I** devices with a measuring function.

Medical devices under Directives can now be **sold indefinitely** without the need for **sell-off provisions** outlined in MDR Article 120.4.

KEY CHANGES AND RESPONSIBILITIES OF THE MANUFACTURERS

The new MDR places several obligations on medical device manufacturers. These are some of the significant changes and responsibilities they must adhere to:

- All medical devices must have a **Unique Device Identification (UDI)** included on their labels. This UDI will be used to track the device throughout the supply chain.

- The **definition** of a medical device has been broadened to include **cosmetic** and **non-medical devices** that were previously not included.
For example, items such as contact lenses, liposuction equipment, devices for cleaning and sterilising, and active implantable technology will now fall under the category of medical devices.

- It is necessary to **translate** all content related to medical devices into the **official languages of the EU member states** where the device will be sold and distributed.

- Many medical devices have been moved up to a higher risk category, and there is now a need for notified body oversight for reusable surgical devices with a **new classification**.

- Manufacturers of medical devices must conduct thorough **clinical evaluations** of their products to ensure they are safe and effective. They are also required to create a **Clinical Investigation Plan** for their entire product line.

- To prove that their products are safe and effective, manufacturers must collect **more detailed clinical data** and adhere to stricter **equivalency standards**.

- **European Medical Database (EUDAMED)** will consist of several integrated electronic systems that will gather and process information about the devices in the EU.
The database facilitates **better access and exchange** of information with all the stakeholders.

LANGUAGE REQUIREMENTS ACCORDING TO THE MDR & ITS IMPACT ON TRANSLATION

The new Medical Device Regulation has introduced stricter **language requirements** for medical devices sold in the European Market.

The new EU MDR imposes this **obligation on the manufacturer** rather than its member states to comply with its language requirements.

The translation must be available in all the official languages of the EU member states they are distributed

Article 10 (section 11) of the MDR states, “Manufacturers shall ensure that the device is accompanied by the information…in an official Union language(s) determined by the Member State in which the device is made available to the user or patient.”

Additionally, the requirement to translate the content related to the medical devices may differ in the same member state depending on the **intended user** of the device. They are classified into:

Lay users: Any individual without formal education in a relevant medical or healthcare profession.

Professional user: Typically, this refers to healthcare professionals

LANGUAGES ACCEPTED IN THE EU MDR STATES

EU Member State	Language	EU Member State	Language
Austria	German	**Italy**	Italian
Belgium	German, French & Dutch	**Latvia**	Latvian
Bulgaria	Bulgarian	**Lithuania**	Lithuanian
Croatia	Croatian	**Luxembourg**	French, German & Luxembourgish
Cyprus	Greek	**Malta**	Maltese & English
Czech Republic	Czech	**Netherlands**	Dutch
Denmark	Danish	**Poland**	Polish
Estonia	Estonian	**Portugal**	Portuguese
Finland	Finnish & Swedish	**Romania**	Romanian
France	French	**Slovakia**	Slovak
Germany	German	**Slovenia**	Slovenian
Greece	Greek	**Spain**	Spanish
Hungary	Hungarian	**Sweden**	Swedish
Ireland	English & Irish		

Kindly note that the information presented in this table is intended solely for reference purposes. To ensure compliance, it is important to seek guidance from the authority of the relevant EU member state in case of any doubts. Additionally, please be aware that the provided information may be subject to updates, and all particulars were accurate to the best of our knowledge at the time of publication.

Language level requirements

Manufacturers have to navigate these **three** language-level requirements to comply with the MDR language requirements

Union level: This involves adhering to generic language requirements and recommendations outlined in the EU MDR

National level: Manufacturers must comply with specific language requirements and recommendations set by individual EU Member States.

Device level: These are specific language obligations based on various factors such as the device's classification, intended users, and content type that manufacturers need to comply with.

Translations are required before the Conformité Européenne(CE) approval

The **CE certification i**s a regulatory standard that verifies that certain products are safe for use and sale in the European Union Ares. Earlier, translations were required after the medical device obtained the CE marking.

However, according to the new EU MDR requirements, translations for some medical device documents, such as Instructions For Use(IFU) have to mandatorily be submitted **prior to obtaining the CE marking.**

Device classification updates

As previously mentioned the MDR broadens the EU's **medical device classification system**. Therefore, medical device manufacturers need to determine the classification ranking of their devices and produce content accordingly.

Some products like contact lenses and cosmetic medical equipment are now considered medical devices. As a result, these manufacturers must adhere to the new MDR guidelines and translate all applicable materials.

Translations and original language must use clear, precise wording

The MDR places significant importance on the safety and quality of medical devices. The end user of the medical device must be easily able to **access** and **understand** all the information related to the medical device.

In this regard, the MDR requires both the **original** and the **translated** documents to be **clear** and **precise**.

Medical device documents must be compatible with the EU database

All the content related to medical devices will be stored in the **European Medical Database (EUDAMED)** to ensure the information pertaining to all medical devices can be stored and exchanged.

Therefore, the manufacturers must ensure that the translators/Language service providers use compatible Content Management Systems and have their own Translation Management Systems.

Higher-quality management systems

As the MDR emphasises quality management and **supply chain transparency**, it places significant importance on utilising robust quality management systems.

Therefore, it becomes essential to collaborate with a reputable language translation provider that holds certifications like **ISO 17100:2015**, signifying their commitment to maintaining high-quality standards.

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ROLE OF AN LSP IN MEDICAL DEVICE TRANSLATION

Medical device translations can be challenging because of the complexities involved in terms of rules and regulations as well as the stringent need to maintain the accuracy and precision of the translation.

However, partnering with a **Language Service Provide**r can help you streamline the process. Here's why choosing an can be beneficial for MDR:

- LSPs have **extensive experience** working on projects of similar nature and have sufficient knowledge about the regulatory requirements.
- They take on the translation process from **start to finish** and guide you through the process.
- **Network of global translators** with subject matter expertise who ensure that the translations are accurate and in accordance with the MDR requirements.
- LSPs leverage an array of **advanced tools and technologies** that aid in the translation process to enhance the translation process and improve efficiency and accuracy.

HOW CAN MILESTONE LOCALIZATION HELP?

Milestone Localization is an **ISO 17100: 2015** language service provider helping organisations across the globe fulfil their language requirements. Our comprehensive range of services includes translation, transcription, localization, interpretation, subtitling, video captioning, and more.

We cater to **diverse industries** such as legal, medical, gaming, software, eCommerce, and others, delivering top-notch language solutions tailored to your specific needs.

A TRANSLATION PARTNER YOU CAN TRUST

- **ISO 17100: 2015** certified
- Dedicated **project manager** for each project
- **Native translators** with subject matter expertise and a minimum of **4+** years of experience.
- **Weighted** word count leverage
- A **4-step** robust quality checking process
- **Accurate** translations delivered on time, every time
- Strict **Non-disclosure** policy
- Globally acceptable **translation certificates**

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OUR MEDICAL DEVICE TRANSLATION SERVICES

Having **extensive experience** working with various companies in the medical and healthcare sector, we have gathered a **network of highly skilled medical translators** well equipped to handle complex and large-scale medical device translation requirements.

Our medical device translation services is available for **all types of medical device classified in MDR**. We are well-equipped to translate all types of documents related to medical devices:

- Instructions For Use(IFUs)
- Device operation manuals and safety manuals
- Packaging & labels of medical devices
- Regulatory documents
- Patient Information Leaflets (PILs)
- Clinical evaluation reports
- Post market surveillance reports
- Clinical trial documentation
- Technical documentation
- Quality management system documents

We ensure the translations meet the language requirements of the **EU MDR** and provide **translation certificates** accepted by all regulatory authorities across the globe.

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