EU MEDICAL DEVICE REGULATION & LANGUAGES

Q&A on the regulation, continued compliance and the impacts on content translations.

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UNDERSTANDING THE IMPACTS OF THE MEDICAL DEVICE REGULATION (EU MDR)

The transition to the EU Medical Device Regulation (EU MDR) marks a significant shift from previously existing regulations. Designed to enhance patient safety and ensure greater transparency in the medical device industry, the EU MDR introduces more stringent requirements, broader oversight, and a robust focus on clinical evidence and post-market surveillance. The new regulations outlined on the EU Commission website contain a series of extremely important improvements including:

- **Enhanced scrutiny for high-risk devices:** Stricter ex-ante control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of EU experts.
- **Strengthened oversight of notified bodies:** Reinforcement of the criteria for designation and processes for oversight of notified bodies.
- **Expanded scope:** Inclusion of certain aesthetic devices that present the same characteristics and risk profile as analogous medical devices under the scope of the regulations.
- **Updated risk classification:** A new system for in vitro diagnostic medical devices in line with international guidance.
- **Increased transparency:** A comprehensive EU database on medical devices supported by a device traceability system based on unique device identification.
- **Implant cards:** Introduction of an implant card for patients containing information about implanted medical devices.
- **Rigorous reinforcement:** A new emphasis on the rules for clinical evidence, including an EU-wide coordinated procedure for authorizing multi-center clinical investigations.
- **Robust post-market surveillance:** Strengthening of post-market surveillance requirements for manufacturers.
- **Improved coordination:** More cohesive communications mechanisms between EU countries in the fields of vigilance and market surveillance.

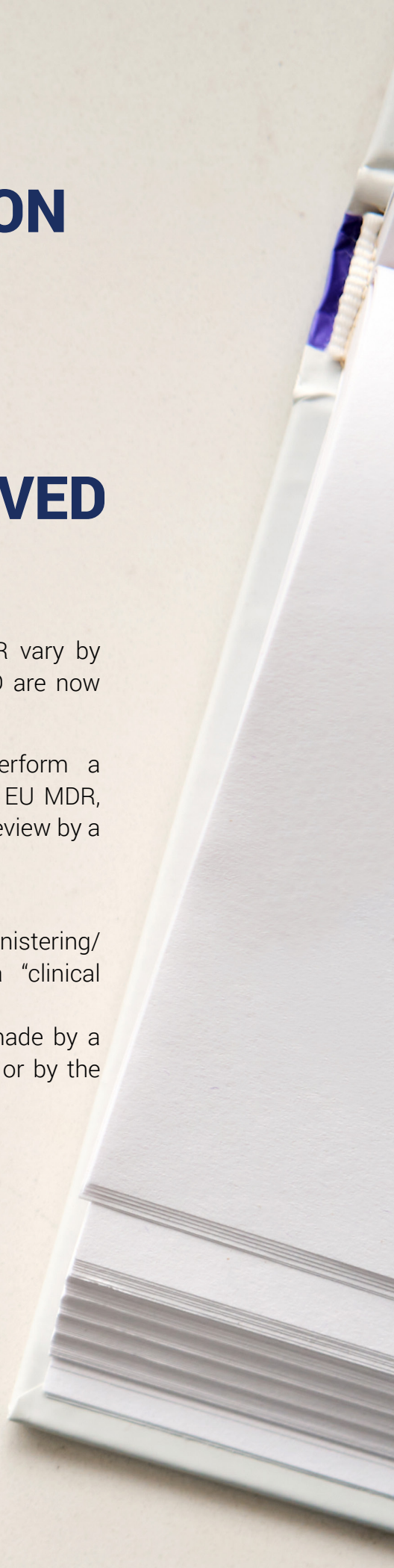
WHAT DOCUMENTATION IS NECESSARY TO DEMONSTRATE CONFORMITY OF A DEVICE TO AN APPROVED AUTHORITY?

Conformity assessment procedures under the EU MDR vary by device class. All devices formerly subject to the AIMDD are now typically classified as Class III under the EU MDR.

Before marketing a device, manufacturers must perform a conformity assessment as outlined in Article 52 of the EU MDR, referencing Annexes IX to XI. The need for a pre-market review by a Notified Body is determined by the device's class.

Specifically:

- Class III and certain Class IIb devices (those administering/removing medicinal substances) may undergo a "clinical evaluation consultation" based on Article 54 criteria.
- The decision for a device to undergo "scrutiny" is made by a Competent Authority as per Article 55, paragraph 2, or by the MDCG/Commission under Article 55, paragraph 3.



CAN ELECTRONIC INSTRUCTIONS FOR USE (EIFU) BE PROVIDED UNDER THE EU MDR AND IVDR?

The European Commission has enacted the Implementing Regulation (EU) 2021/2226, which governs the conditions under which certain medical devices, regulated by the Medical Devices Regulation (MDR), can have their instructions provided in an electronic format. This new regulation effectively replaces the former EU Regulation (207/2012).

Based on current regulations, Implementing Regulation (EU) 2021/2226 allows electronic instructions for certain devices under the MDR, which includes:

- Implantable and active implantable medical devices and their accessories.
- Fixed installed medical devices and their accessories.
- Medical devices fitted with a built-in system displaying the IFU.
- Software covered by the MDR.

The electronic instructions for use can be provided if:

- The devices are intended exclusively for professional use.
- It's not foreseeable for non-professionals to use them.

For software under the MDR, these conditions don't apply and the software itself can display electronic instructions.

However, it's important to note that EU Regulation 2021/2226 on electronic instructions for use does not apply to IVDs. Annex 1, Chapter III, Section 20.1 of the IVDR specifies when manufacturers do not have to provide the IFU in paper format:

"When the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the device is intended for near-patient testing."

HOW DO THE REGULATIONS DIFFER FOR DEVICES THAT ARE INTENDED FOR USE BY PATIENTS VS. MEDICAL PROFESSIONALS?

The EU MDR does not distinguish between lay use and professional use with regard to requirements for device design, manufacturing, risk, and safety. The principal difference is in the information provided to the user. The MDR requires information to be tailored for a lay user's understanding, factoring in readability and reading levels. Identification of the user and the appropriate human factors applicable should be part of the usability evaluation and product and labeling validation.

DO THESE DOCUMENTS NEED TO BE TRANSLATED INTO EVERY OFFICIAL UNION LANGUAGE?

Technical files do not need to be translated into the EU-27 official languages. Each manufacturer should work with their Notified Body to agree upon the languages necessary for the Technical File review.

Final product labeling also does not need to be fully translated to submit a complete Technical File. However, the Notified Body will expect to see procedures regarding how translations of labeling are managed and implemented, especially with regard to ensuring products are not distributed to a particular country without the necessary translated labeling being provided, either in the sales pack or on the internet as applicable.

WHAT ADDITIONAL CONTENT MUST BE TRANSLATED AS A RESULT OF THE MDR CHANGES?

There are no additional translation requirements under the EU MDR. In the EU MDR, the requirement is specifically:

"Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient." (Article 10, paragraph 11)

While this is not a new requirement, there may be additional scrutiny by the Notified Bodies to ensure economic operators responsible for placing a product in a market are providing the required local languages. However, the languages required and any exemptions for professional use, have not been modified by the EU MDR and remain the sole responsibility of each Member State.

Note: In this case, economic operators could be the manufacturer, the authorized representative, or the distributor.

IS IT MANDATORY TO TRANSLATE SOFTWARE APPLICATIONS USED IN HOSPITALS BY PHYSICIANS AND TECHNICIANS IF THE USERS ARE PRESUMED TO BE FLUENT IN ENGLISH?

Each Member State has specific rules regarding official local language requirements and whether there are any exemptions for other languages based on criteria such as professional use. Because English may not be the only alternative for professional use in some markets, manufacturers cannot presume technical users are fluent in any language other than the local language.

Manufacturers should apply their risk management system to determine the usability of any medical device including its instructions for use. All aspects of the use of the product should be considered, including but not limited to:

- technical skill and qualifications of the intended user
- required training before use of the product
- providing instructions in a local language for the use of software in another language
- the risks related to the use and misuse of the software

Manufacturers may also request derogations from a Member State's Ministry of Health to use a language other than the one normally required. Such a request should be predicated upon usability information that indicates another language is suitable for the intended user. A derogation may or may not be granted.

WHAT ADDITIONAL LANGUAGES MUST BE TRANSLATED AND HOW DOES THAT CHANGE GIVEN TYPE OF CONTENT (I.E. IFU, LABELING/ PACKAGING, ETC.)?

All labeling (IFU/DFU, sterile/sales pack labels, device markings) must be provided in the local languages specified by the Member States unless the information is provided in symbols.

Practically speaking, this means that if a Member State allows any other language besides the official language, the manufacturer could pick between any allowed language (e.g. if English, German, or Swedish is allowed in place of the official Member State language). Likewise, if no exemptions are allowed, then the official language is required. This also means that if there is more than one official language for a Member State, and no exemptions are permitted, then the labeling must be provided in all official languages (e.g. official languages in Belgium are Dutch, French, and German).

Symbols are an extremely useful way to deal with the limited amount of space on labeling such as package labels or device markings. Using symbols eliminates both the need for text and the need to translate text.*

Device markings specifically should be analyzed for how they can be best marked considering their size and material composition, the service life of the device, and its use conditions (e.g. sterilized/cleaned between use, implantable devices, etc.).

When symbols are used, preference is given to symbols from harmonized standards or international standards. Manufacturers should consult ISO 15223-1, IEC 60417, and ISO 7000 to identify symbols appropriate for use with medical devices. All international standards symbols with few limited exceptions, can be accessed by the public for free. In order to access native versions of the files for use in their labeling, Manufacturers need to subscribe to the particular standards that contain them.

Under the EU MDR other symbols not in standards can be used if both explained in the IFU and validated for usability during design controls.*

*Note: Some geographies, such as the US, limit the use of symbols without accompanying text. If a symbol not from a standard is used, those geographies will still require accompanying text in the required local language, which may require translation depending on the market(s).

HOW IS MDR IMPACTING THE SSCP CLINICAL DELIVERABLE AND WHAT IS THE SUBSEQUENT IMPACT ON TRANSLATION?

The Summary of Safety and Clinical Performance (SSCP) is required for implantable devices (regardless of class) and Class III devices. (Article 32).

The EU MDR does not require that this document be translated. However, it does require that it is *"…written in a way that is clear to the intended user and, if relevant, to the patient…."*

It is possible that guidance documents may be forthcoming from industry associations or the MDCG/Commission regarding the conditions under which the SSCP or a patient facing portion of it should be translated and into which languages.

Further implementing acts related to the SSCP may also be anticipated as mentioned in Article 32, paragraph 3.

ARE THERE ANY RESTRICTIONS ON WHAT TYPE OF SYMBOLS WE CAN USE?

See above for translations (#10). Preference is given to symbols from harmonized standards or international standards. Other symbols can be used if both explained in the IFU and validated for usability during design controls.

ABOUT ARGOS

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