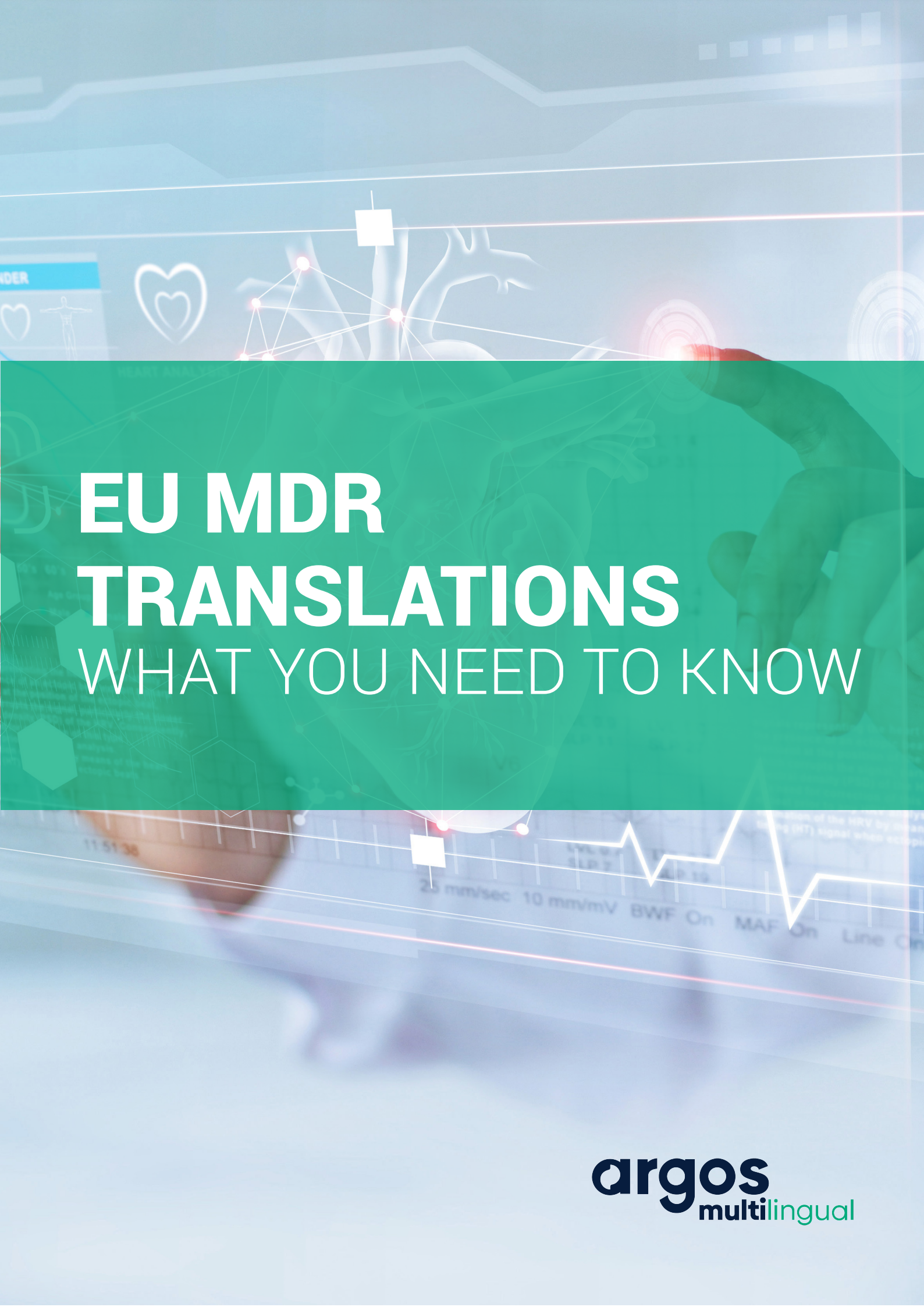

EU MDR TRANSLATIONS

WHAT YOU NEED TO KNOW

argos multilingual

CONTENTS

Medical device manufacturers (MDMs) have a variety of resources to ensure compliance with the EU Medical Device Regulation (MDR). However, as a localization manager, you may be wondering what the MDR means for translation and what types of content you should prepare your team for. This guide will provide insight into what you should expect and help you deliver translations under the MDR.

Let's start with the basics. The EU MDR impacts the following countries and languages:

COUNTRY	LANGUAGE
Austria	German
Belgium	Dutch, French, German
Bulgaria	Bulgarian
Croatia	Croatian
Cyprus	Greek, Turkish
Czech Republic	Czech
Denmark	Danish
Estonia	Estonian
Finland	Finnish, Swedish
France	French
Germany	German
Greece	Greek
Hungary	Hungarian
Ireland	Irish, English
Italy	Italian
Latvia	Latvian
Liechtenstein**	German
Lithuania	Lithuanian
Luxembourg	Luxembourgish, French, German
Malta	Maltese, English
Netherlands	Dutch
Norway**	Norwegian
Poland	Polish
Portugal	Portuguese
Romania	Romanian
Slovakia	Slovakian
Slovenia	Slovenian
Spain	Spanish
Sweden	Swedish
Switzerland**	French, German, Italian
United Kingdom*	English

*The UK's regulatory framework mirrors many aspects of the EU's regulations but some differences exist.
**These countries are included in the European Free Trade Association (EFTA) and are not technically part of the EU. However, through the EEA agreement, they can participate in trade with the EU with respect to medical devices and medicinal products. Several of these countries are bringing their requirements in line with the MDR so that they can continue to participate in this trade.

View the EU MDR in a variety of languages here.

THE CONTENT FOR DELIVERY UNDER MDR FALLS INTO A FEW MAIN CATEGORIES:

1. Requirements that do not change
2. New content for delivery under MDR (required)
3. New content for delivery under MDR (occasionally/sometimes required)

Let's start with the easiest:

REQUIREMENTS THAT DO NOT CHANGE

Currently, medical device manufacturers are required to supply translations for labeling, instructions for use (IFUs), operator's manuals, and field corrective actions. The content must be supplied for all languages required by the member states in which devices are marketed and sold. This requirement remains unchanged and should not pose challenges to any MDMs already selling devices in Europe.

NEW REQUIRED CONTENT FOR DELIVERY UNDER THE MDR

For implantable devices, both an implant card and patient information must be provided to the recipient of the device at the time of implantation. The MDR specifies that this must be available in "commonly understood" language. The requirements for the content of these materials align closely with the existing IFU and labeling requirements, detailing intended use, warnings and precautions, and standard product information. When translating these materials, it's vital that MDMs communicate that the audience and level of education for the consumer may be different, depending on whether the device is intended for use at home or in a clinical setting.

Declarations of conformity supplied by the notified body are required to be available in all languages for member states where the device is marketed and sold.

In addition to new patient materials, MDMs are required to provide a synopsis of the clinical investigation and a summary of the safety and clinical performance in the languages of member states. These synopses will be uploaded to the EUDAMED database and will be part of the submission materials. However, they will not be available to the general public.

The initial launch date EUDAMED was March 26, 2020 but there have been several delays. Currently, the use of EUDAMED is not yet mandatory or required, but some modules are available and can be used voluntarily. However, mandatory use will begin 6 months after the entire EUDAMED system has been declared fully functional following an independent audit and the publication of a Commission notice in the Official Journal of the European Union (OJEU).

The UI will support all member-state languages, but some fields are expected to necessitate some translation.

The delay of EUDAMED's go-live date has no bearing on other MDR compliance requirements.

CONTENT OCCASIONALLY REQUIRED FOR DELIVERY UNDER THE MDR

NOTES ON TRANSLATION REQUIREMENTS UNDER THE MDR

Safety Information in Article 10

The MDR introduces a key provision in Article 10, item 14, which could alter existing practices in medical device documentation. Specifically, any EU member state where a device is sold can demand translations of all documentation verifying the device's safety and compliance.

Technical Documentation under Annex I and Article 52

Annex I of the MDR details the essentials for technical reports. Separately, Article 52 empowers member states to ask for an array of documents, including technical documentation, audit details, assessments, and inspection findings. Notably, these technical documents must feature annually updated post-market surveillance reports. Often, these sensitive reports exist only in the manufacturer's primary language, prompting Medical Device Manufacturers to deliberate: should they proactively translate these reports into all applicable languages or address translation on a case-by-case basis?

Risk Assessment

MDMs may also wish to evaluate their level of risk for the translation of technical documentation against their current supplier agreements to make sure that they are well-protected. There could be new risks around the accidental or intentional breach of critical intellectual property, especially for devices that have not yet been approved for market.

Timing and Frequency of Updates

What is currently unclear is how often the member states will require MDMs to produce these translations, or how much time they will be given to comply with requests. However, it is safe to assume that if the requesting member state finds the documentation lacking, they have the right to stop sales of the device until their questions or concerns are satisfied. Accordingly, there is likely to be a high level of urgency and concern about accuracy for these types of translation requests. Any error in this content is likely to be highly visible, and there will be a real financial impact for MDMs dealing with translation quality issues.

Translation Triggers

Translations for documentation supporting device safety will likely be requested when there are serious patient-related adverse events, and each notified body may handle this type of documentation request a bit differently during the submission.

This is an area likely to evolve over time and may require more or less translation depending on the approach taken by each notified body.

MDMs should take the time to set up and document a process for this type of request before it becomes an urgent project. Speed and quality will be very critical to this process, since incomplete or inaccurate translations could cause investigational delays or market holds.

Finally, MDMs should be very clear with their LSPs how they want this content handled, for example:

- Is it permitted to run this content through a machine translation (MT) engine?
- Should this content be part of their standard translation memory (TM)?
- Or should this content be segregated to limit the number of individuals with access to their intellectual property?

Notified Bodies

Notified bodies are organizations designated by EU member states to assess the conformity of medical devices. These regulatory bodies are being qualified on a site-specific level. Each notified body must advertise the language(s) they will accept submission documents in, and submission materials must be provided to the notified body in one of their accepted languages. There are currently 40 MDR certified notified bodies fully approved and the EU has 24 official languages.

MDMs doing business in languages other than those in the official list will need to select which languages they will translate submission documents into and then decide which language will be their "pivot language," which serves as the reference for all subsequent translations. This could create some new challenges for companies in regions that do not have approved notified bodies.

Since notified bodies are permitted to request any documentation required to approve the device — including technical documentation, audit assessments, inspection materials, and internal procedures — this could create additional translation needs for companies not doing business in the language of their notified body. For example, a company doing business in Japanese may need to invest time and money translating their supporting documentation into German, Dutch, or English. MDMs affected by these requirements may wish to have an established pivot translation process in place with their LSP.

While manufacturers are responsible for issuing the Declaration of Conformity (DOC) to assert their product's compliance with relevant regulations, Notified Bodies provide certification after assessing the product. This certification is used as part of the manufacturer's Declaration of Conformity. MDMs are responsible for issuing the DOC in one of the member state languages.

Finally, notified bodies have been given a new responsibility – ensuring translation quality and consistency. Annex 7, Section 2.2 states that notified bodies are responsible for ensuring that translations of the same document contain the same content. The MDR does not provide guidelines for this requirement and notified bodies often have the flexibility to establish their own processes as long as they comply with EU MDR standards. This can lead to some variance in how different notified bodies interpret and act on parts of the regulation. Since this requirement could result in added feedback during the approval process, MDMs should be prepared with a strategy to manage and address this feedback.

Interestingly, distributors have also been given the responsibility of ensuring they have procedures in place to ensure that translation of all information is accurate. Depending on how each distributor interprets this requirement, this could also create some additional feedback for translation managers that will need management post-delivery.

Expert opinions are not called out specifically in the MDR as requiring translations. However, the new expert opinion process may necessitate them. The call for experts specifies that the expert panel members must be able to actively participate, deliberate, and write reports in English. While businesses operating in English may not need translations, those who work languages other than English might.

Within 14 days of an application, the notified body is required to convene an expert panel to create a joint assessment team. The MDR specifies that member states should share experts, but it's reasonable to expect that not all experts will share a common language or be able to read the submission materials for every device. Within 90 days of appointment, the joint assessment team will convene to review the submission materials.

It's likely that some submission materials may need to be translated to facilitate the expert panel review. Although not specifically spelled out in the MDR, this is likely one of the reasons MDMs may be asked to translate safety and conformity information.

SUMMARY

While MDM regulations make some expectations much clearer, ambiguity remains around the translations that will be needed, and whether they will affect some or all devices. To best prepare, MDMs will want to evaluate their translation ecosystem to make sure that it is ready to adapt to the new requirements.

FAQ

WHAT IMPORTANT DATES SHOULD I BE AWARE OF?

MAY 26, 2017
MDR 2017/745 and IVDR 2017/746 regulations came into effect.

NOVEMBER 26, 2017
Notified Bodies were allowed to apply for designation under both MDR and IVDR.

MAY 26, 2021
Deadline for most devices to comply with MDR, except those covered by the extended transition period.*

MAY 26, 2022
IVDR deadline. All IVD products must be compliant with the IVDR to be sold and marketed in Europe.

MAY 26, 2024
Transition period ends for legacy devices that do not meet the conditions for extended transition.

MAY 26, 2024
Deadline to submit an application for MDR conformity assessment and to have an MDR Quality Management System (QMS) in place.

SEPTEMBER 26, 2024
Deadline to sign a written agreement with a notified body and transfer appropriate surveillance to an MDR notified body (where applicable).

MAY 26, 2026
End of derogation for class III custom-made implantable devices.

DECEMBER 31, 2027
Transition period ends for class III and class IIb implantable devices, unless they have specific exemptions (like sutures).

DECEMBER 31, 2028
Transition period ends for other devices, including class IIa, class I sterile/measuring devices, and devices that require the involvement of a notified body for the first time under MDR.

*Initially, the EU MDR deadline was set for May 26, 2020. However, in response to the COVID-19 crisis, the European Commission proposed a one-year postponement of the application date.

WHICH NOTIFIED BODIES ARE APPROVED? IS MY CURRENT NOTIFIED BODY SEEKING APPROVAL OR HAVE THEY DECIDED TO OPT OUT?

Orielstat is keeping a list that was last updated on July 20, 2023. The best way to check on the status of your current notified body partner is to contact them directly.

WHAT LANGUAGES ARE CURRENTLY BEING ACCEPTED BY THE NOTIFIED BODIES?

Not all notified bodies have published their language requirements. The list of languages provided here may not be complete, and we recommend contacting your notified body to confirm that they accept submissions in the language your company does business. We are assuming that notified bodies will accept content in the native language of their location/region if they have not published guidelines, and we are making some assumptions on language acceptance based on the location of the notified bodies that have not yet published.

Those that have published their MDR requirements are:

- English: BSI Netherlands, Dare, IMQ, BSI UK
- Dutch: Dare
- German: DEKRA (Germany and Netherlands), TUV Rhineland and SUD, MEDCERT
- Italian: IMQ

It is advisable to contact your notified body to ensure they accept submissions in your company's primary language. In instances where notified bodies haven't published guidelines, it is logical to assume they accept content in the primary language of their location. However, to avoid any inconvenience, direct communication with the body in question is best.

WHAT IS THE IMPACT OF THE NOTIFIED BODY SHORTAGE?

Many experts believe the notified body shortage will be the main hurdle to compliance, however it is not as bad as initially thought.

According to this article, there has been a significant increase in MDR and IVDR applications and certifications, indicating a proactive response from manufacturers. The European Commission's survey reveals that regulatory bodies have increased their capacity, leading to fewer application refusals due to insufficient resources. However, experts advise caution. They highlight potential bottlenecks in the certification process and the importance of timely applications to ensure a smooth transition. Clear communication between regulatory entities and manufacturers is crucial, as any delay in the MDR transition might affect global production processes.

Because of these medical rules in Europe, many companies are choosing to get their products approved elsewhere first. Before, they often went to Europe first because it was quicker. Now, more companies are going to the US for their first approvals. This means the US system is getting busier, which might lead to delays. Today many companies are having to think differently about where to go first to get their products on the market.

WHERE CAN I LEARN MORE?

You should, of course, start with the directives themselves (linked below for all languages). The notified bodies also have a wealth of resources. We suggest you also look at the websites and guidelines published by your notified body, and some additional helpful links are included.

1. MDR Directive (all languages)
2. IVD Regulation (all languages)
3. RAPS news regarding Notified Body shortage
4. BSI Whitepaper comparing MDD and MDR **(gated)**
5. DEKRA FAQ
6. MedTech Views: IVDR/MDR transition periods
7. Emergo EUDAMED white paper
8. Epista Five-part series on IVDR
9. Call for Experts
10. Technical documentation and EU declaration of conformity

ABOUT ARGOS

Argos Multilingual is a global language solutions provider with experience in the life sciences, industrial manufacturing, and software/hardware industries. Our business is built on three core values - quality at source, a partnership approach, and technology agnostic solutions. We are committed to giving you freedom of choice while providing customized strategies to fit your business needs, and we are ISO 9001, ISO 17100, EN ISO 13485, and ISO 27001 certified. With production centers in Krakow, Poland and Colorado, USA, we provide value through dedicated customer service and subject matter expertise in your industry.

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