EU IVDR TRANSLATIONS

WHAT YOU NEED TO KNOW

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WHERE TO BEGIN

There are many resources available for in vitro diagnostic device manufacturers working to comply with the IVDR. However, as a localization manager, you may be wondering what the IVDR means for translation and what types of content you should prepare your team for. This guide will help you deliver translations under the requirements and better understand what to expect.

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

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.

One of the biggest challenges manufacturers have navigated under the EU's IVDR regulations is that many devices which previously fell under the "self-certification" category must now be submitted to a notified body for approval. The IVDR provides considerably more guidance to IVD manufacturers as to how their business should be conducted and how much clinical investigation is required in order to submit devices for approval. No products were grandfathered in and every product on the market must be prepared for approval.

New device classification is detailed in Annex VIII of the IVDR regulations. Class A devices, including general laboratory products and media, specimen receptacles, and devices intended to be used in diagnostic procedures, retained their self-certification status. However, Class B-D devices, which include all other devices with patient contact or the potential to impact patient outcomes, were changed significantly.

Manufacturers of Class A devices must carry out appropriate assessments, but are not required to submit to a notified body. Self-certified devices (Class A only) represent only 20% of the market under IVDR, as opposed to 80% of the market previously. Class B-D devices must submit to a notified body for approval, and overall regulation will be managed in a way that is proportionate to the risk associated with the device, with some of the regulations coming into force at different times to allow for tighter regulations sooner on Class D devices (see article 115 for details). I

IVDR requires the translation of the following items:

- Labeling information and instructions for use (compulsory)
- Field corrective actions (compulsory)
- Patient information, where the device is intended to be used for self-testing (compulsory)
- Information demonstrating the safety and conformity of the device (upon request)
- Declaration of conformity (compulsory)
- EUDAMED free-text fields (compulsory)
- Technical documentation, audit reports, assessment and inspection reports (upon request)

FAQ

WHAT ARE THE KEY DATES FOR IVDR?

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.

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 regulations 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, which are 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 we've included some additional helpful links here.

1. MDR Regulation (all languages)
2. IVDR 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

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