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THE EU MEDICAL DEVICE REGULATIONS UNDER THE MICROSCOPE:

WHAT DO THEY MEAN FOR TRANSLATIONS?

CONTENTS

AN INTRODUCTION TO EU MDR AND IVDR

In May 2017, two new European Regulations concerning medical devices and in vitro medical devices were adopted. European Union Medical Device Regulation (EU MDR) and European Union In Vitro Diagnostic Regulation (EU IVDR) impact the whole medical device supply chain; since its adoption, companies in the medical device industry have been proactively integrating compliance measures into their global strategies.

Since they were first issued, the regulations have been continuously evolving. Directive 2001/83/EC, Regulation (EC) No 178/2002, and Regulation (EC) No 1223/2009 have been amended. In contrast, Council Directives 90/385/EEC and 93/42/EEC have been replaced by the Medical Devices Regulation (EU) 2017/745. The In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 supersedes the Commission Decision 2010/227/EU and the earlier Directive 98/79/EC.

WHY THE REGULATION?

The previous regulatory framework had been in place since the 1990s and updated intermittently. European authorities recognized the need to update and improve risk management practices to ensure the safety of medical devices sold in the European Union. This led the European Commission to introduce two legislative proposals in September 2012. These proposals underwent five years of consultation and negotiation, culminating in a new set of regulations that impact manufacturers, distributors, notified bodies, importers, the supply chain, and member states.

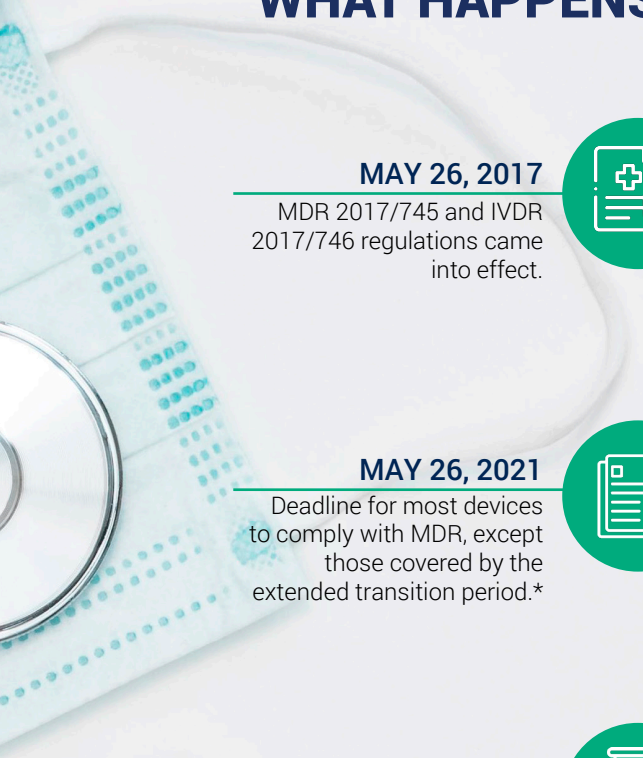
The new regulations are wide-ranging, with the full English version (including annexes) running more than 180,000 words, and available in 24 EU languages, which is helpful for those whose native tongue is not English.

THE TIME TO ACT IS NOW

Because of the regulations' complexity and scope, the European Parliament approved staggered extensions for the MDR transition, based on the risk associated with medical devices. It's essential to understand that these extensions don't necessarily grant manufacturers more time for preparations. The MDR transition for certain devices now has extended deadlines, such as December 2027 for high-risk devices and December 2028 for those with a lower risk classification.

If you haven't started your preparations yet, the time to act is now. Waiting can mean missing crucial deadlines and facing potential bottlenecks with notified bodies, which will delay your time to market.

WHAT HAPPENS WHEN?



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.

THE REGULATIONS IN A NUTSHELL

EUDAMED

A significant advancement under the new framework is the creation of EUDAMED. This comprehensive database encompasses all medical devices sold within the European markets. Designed to be accessible in all 24 official languages of the European Union, EUDAMED's primary goal is to provide swift and transparent identification and monitoring for each medical device in the EU by registering their unique device identifiers (UDIs).

CURRENT STATE OF EUDAMED

While EUDAMED was initially set to launch in 2020, it faced several delays. As per the new timeline issued by the European Commission in June 2022, a minimally viable version of EUDAMED is projected to be developed by the last quarter of 2023. The first two quarters of 2024 will be dedicated to an independent audit of its functionalities.

EUDAMED is divided into six key modules:

1. Actor registration
2. Unique device identification (UDI) / device registration
3. Notified bodies and certificates
4. Clinical investigations and performance studies
5. Vigilance and Post-Market Surveillance
6. Market Surveillance

After a successful audit of the database's capabilities, a declaration regarding EUDAMED's full operational status will be made in the Official Journal of the European Union (OJEU) in the second quarter of 2024. Following this announcement, a six-month transitional phase will start. The transitional phase is expected to conclude by the end of 2024 when several modules will become mandatory. All modules are expected to be mandatory by the second quarter of 2026.

UNIQUE DEVICE IDENTIFICATION SYSTEM

For manufacturers who do business in the United States, the proposed process for Unique Device Identification (UDI) should feel quite familiar – the MDR and IVDR UDI implementation has been made using lessons learned from the US Food and Drug Administration's (FDA) UDI implementation. For those unfamiliar with the FDA's system, UDIs and EUDAMED are systems that allow for easier traceability and recall. The systems also enable centralized reporting and access to essential product information.

MAKING UDIs HAPPEN

Manufacturers will need to integrate technology to maintain updated UDI-related information such as post-market clinical investigation data and performance studies. Manufacturers also need to include a UDI on every product label, which requires planning, as label space may be in short supply.

One of the benefits is that once a manufacturer's products have been assigned a UDI and the relevant information has been supplied to EUDAMED, device registration is done at the EU single market level, making multiple national level registrations a thing of the past.

MEDICAL DEVICE CLASSIFICATIONS

As mentioned earlier, MDR and IVDR shine a spotlight on every aspect of regulation from the perspective of risk management. Medical Device and IVD classification has not escaped this scrutiny, and there are many devices that notified bodies need to check prior to entry into the European Market.

Manufacturers must perform thorough conformity assessments to determine whether their devices meet requirements for relevant classifications prior to submission to notified bodies.

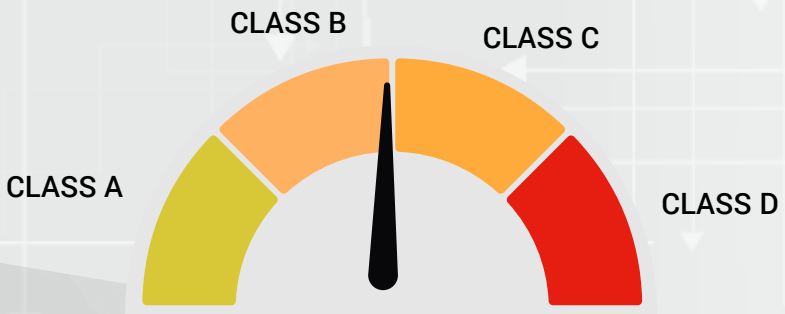
LISTS ARE REPLACED BY RULES

Previously, the system relied on lists. Now, the regulation introduces rules that evaluate the devices' risk to patients, their function, and their intended use. This classification results in four categories for medical devices:

1. Non-invasive
2. Invasive
3. Active
4. Innovative devices that include other substances

The new regulation completely overhauls the IVD classifications. These classifications follow seven rules based on the International Medical Device Regulators Forum (IMDRF) guidelines (formerly the Global Harmonization Task Force (GHTF)).

IVD products fall into one of four categories: A, B, C, or D. Class A products pose the least risk, while class D products pose the highest risk.



STANDARDIZATION: GOOD NEWS?

It's not just about bureaucracy. Building on the foundations established by the IMDRF, the shift to risk-based decision making has transitioned clinical trials in multiple member states to a single coordinated assessment that is aligned with international classification practices.

However, the terrain is proving challenging for IVD manufacturers. The European Commission's recent update reveals that over 80% of previously self-certified IVDD devices now require notified body involvement under the IVDR. This data contrasts with ProClinical Life Sciences initial estimate that 10-15% of IVDs would need assessment by notified bodies. Now, the real-world situation indicates that a substantial majority of devices are subjected to this rigorous assessment process. Whether it reaches the projected 85-90% remains to be seen, but the current trend is certainly upwards.

Furthermore, the regulatory framework includes many products that are designated as "products without an intended medical purpose." Examples include aesthetic products such as facial dermal fillers and contact lenses. These items, now part of MDR Annex XVI, are subject to stricter regulations.

SELF-DECLARATION

According to Annex VIII of the MDR and Annex VII of the IVDR, a risk matrix determines whether conformity assessments can be carried out internally for certain low-risk devices like tongue depressors, disposable gloves, or specific IVD reagents, or whether they need to be assessed by a notified body.
Once a manufacturer has obtained a declaration of conformity for a product, they are authorized to use the CE mark.

CLASSIFICATION NEXT STEPS

These changes impact how both current and future devices are classified, affecting various areas of business, including manufacturing, clinical evidence collection, and conformity assessment.

Manufacturers are advised to consult appropriate specialists to understand the new classification system, determine which parts of their portfolio will be affected, and update technical documents in readiness for conformity assessments. This may also lead to increased translation requirements. Changes to technical documentation and file dossiers will likely affect all target markets, so speak to us about building a language strategy ahead of time to ensure compliance across all your chosen markets.

PREVENTIVE / PROACTIVE POST-MARKET SURVEILLANCE

The recurring theme of risk management in MDR and IVDR also extends to continuous safety improvement throughout a product's life cycle. In practice, this means that manufacturers are responsible for monitoring and reporting on a series of ongoing surveillance and control areas in order to diagnose and predict issues, resulting in continuous preventive and corrective action reporting.

Additionally, there are requirements related to post-market studies outlined in Section 1 Chapter VII of both regulations:

- Periodic Safety Update Reports (PSURs): These reports involve the analysis of post-market surveillance data to assess the safety of medical devices.
- Post-Market Clinical/Performance Follow-Ups (PMCFs/PMPFs): These measures ensure ongoing revision and evaluation of clinical and performance aspects of medical devices.

These regulatory changes underscore the importance of maintaining the safety and performance of medical devices throughout their life cycle.

QUALITY MANAGEMENT

The regulations make manufacturers responsible for demonstrating an effective quality management system (QMS). Key to this is how they exhibit a risk-based approach to decision making.
Section 2, Chapter II, Articles 10 and 22 of the regulation called "Economic Operators" examines supply chain regulation. This needs to be evidenced in investigation, diagnosis, monitoring, control, prediction, and prevention activities, and is specifically required in the monitoring of risks for any tasks that a manufacturer delegates to its third-party suppliers.

SUPPLY CHAIN AND ISO 13485:2012

While the current ISO standard for Medical Devices, ISO 13485:2012, is not stipulated as compulsory at this time, it is the accepted industry standard. Because of this, ISO 13485 is currently perceived as the most compatible system, not least because the standard is explicit in its requirements for the effective selection and control of tasks performed by third-party suppliers. By ensuring that their supply chains are ISO 13485 certified, manufacturers lessen their exposure to risk. They can also begin to manage the requirements laid out in the new regulations. Of course, manufacturers are urged to discuss the finer details of compatibility of their own QMS implementation with their certification bodies.

Along with a small number of other LSPs, Argos Multilingual is certified to the ISO 13485:2012 standard.

CONTROVERSIAL NEW RESPONSIBILITIES FOR OTHER STAKEHOLDERS

Importers and distributors also have specific legal oversight responsibilities. Authorized representatives and importers need to make checks to a host of additional areas. These include not only CE marks, labeling, and conformity assessments, but also post-market Surveillance and recalls. Most controversially, they are also required to decide whether products comply with the regulations before either importing or refusing to import a product.

In the case of authorized representatives who are a subsidiary of a manufacturer (not an unusual arrangement), there is significant potential for conflicts of interest, as it is their responsibility to issue warnings to manufacturers and even report them to the authorities for non-compliance, which may make existing arrangements awkward.

DISTRIBUTORS: INCREASED LEGAL LIABILITY

Distributors are subject to much greater legal liability for the products that are in their care. They will need to meet many of the same obligations as importers and authorized representatives, but without an obligation to label and without exposure to new risks.

STEPS TO MITIGATE RISK

These obligations introduce stakeholders to a much higher level of risk. Because of this, importers, authorized representatives, and distributors need to carefully analyze their roles and responsibilities as well as their exposure to new risks.

In practice, importers and distributors are taking legal advice in order to renegotiate existing contracts with manufacturers, while ensuring that they have suitably robust and informed teams and processes in place to deal with the new regulations. This will often mean that they need to charge more for the services they provide.

Manufacturers would do well to scrutinize existing contractual relationships very carefully as there is significant responsibility overlap between the different roles, and manufacturers need to be very wary of hidden potential risks. Despite being a few years old, Erik Vollebregt's entertaining and insightful Medical Devices Legal blog perfectly summarizes the situation:

> "It becomes more important than ever to organise your supply chain contractually in a way as to avoid surprise, e.g. because a distributor decides to issue a local recall for a not so profitable product, that will be visible for every authority in the EU via EUDAMED and may spin off into something of epic proportions."

He goes on to conclude that manufacturers need to force information sharing across the supply chain in order to help with the division of responsibilities and reduce the potential for any "epic spin offs."

WHAT ABOUT TRANSLATIONS?

Given the all-encompassing nature of the MDR/IVDR regulations, it is surprising that translation and language requirements are only referenced about 60 times. Manufacturers should not get lulled into a false sense of security, however, as translation needs are likely to increase as a result of the legislation, for example:

- UDI requirements impact labeling layouts, making it essential that new designs take localized text expansion into account.
- Any reclassifications to your products may result in significant changes to your technical documentation, which will need to be translated to the languages of your target markets.
- Applications for clinical investigation and analyses of serious incidents and corrective actions may also require translation.

WHO DECIDES WHICH LANGUAHES NEED TRANSLATION?

Competent authorities in each member state will confirm the correct languages you need to translate into for each market. They will also determine what device information (IFUs, labels, documentation demonstrating conformity) will need to be translated.

E-LABELING IS STILL AN OPTION

Regulation (EU) 207/2012, which allowed manufacturers to offer paper-based instructions electronically, was repealed and replaced in 2022 by Regulation (EU) 2021/2226 to better align with the MDR and emphasize transparency and user notification.

Under this regulation, eIFUs can be provided for specific devices and under certain conditions, such as devices intended exclusively for professional users and where use by other persons isn't foreseeable. For software, eIFUs can be provided with the software itself.

Other requirements include:

- Manufacturers are responsible for creating systems to inform device users of updates or corrections for their specific device.
- The availability duration of eIFUs be based on whether a device has a defined expiry date or not.
- New definitions about the information needed to access eIFUs, including the use of Basic UDI-DI and/or the UDI-DI (Unique Device Identification - Device Identifier) of the device.
- Rules for websites providing eIFUs, ensuring protection against unauthorized access and content tampering, in line with GDPR.

Regulation (EU) 2021/2226 emphasizes the importance of eIFUs in reducing paper waste and costs, as well as overcoming the logistical challenges associated with paper IFUs.

NEXT STEPS

ONE LESS THING TO THINK ABOUT?

The regulation outlining Economic Operators (Section 2, Chapter II, Articles 10 and 22) makes risk management in your supply chain one of your high priorities. Being able to rely on a properly certified language service provider such as Argos Multilingual can help you focus on the many other priorities you have as an MD or IVD manufacturer.

As we have illustrated, the MDR and IVDR have introduced substantial changes to the operation of the medical device market. This regulation affects multiple parts of the supply chain, with the ultimate objective of enhancing safety and minimizing risks.

GET MOVING NOW!

Even though the transition periods have been extended, there's no time to lose.

Legislation continues to be issued and refined, and regulations continue to change. While this might sound like the regulations have become a moving target, changes can actually help add clarity where there is currently ambiguity. One thing is clear - it is the responsibility of all stakeholders to stay informed about any changes as they happen.

HOW TO START?

All stakeholders are urged to build steering groups to formulate a thorough action plan for implementation — if this hasn't been done already. These groups should be diverse, regularly share knowledge, and interpret the legislation from all available angles to fully assess business impact.

Some areas of the business are obvious inclusions to the steering group, such as compliance, quality, legal, and regulatory teams. Other stakeholders might not be obvious, but can provide a different perspective on the opportunities and risks in the regulations. Consider including representatives from operations, IT, authoring, marketing, and labeling, plus some of your key suppliers like publishers and language service providers.

Your strategic steering group will need to perform exhaustive gap analyses that assess risk and opportunity, as well as portfolio assessments for reclassifications to both existing and planned products. ROI calculations, supply chain analyses, risk matrices, and budgeting will all need to be reviewed for your transition to be a success.

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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