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Designing devices with European Medical Device Regulation (EU MDR) in mind

Medical Materials & Technologies

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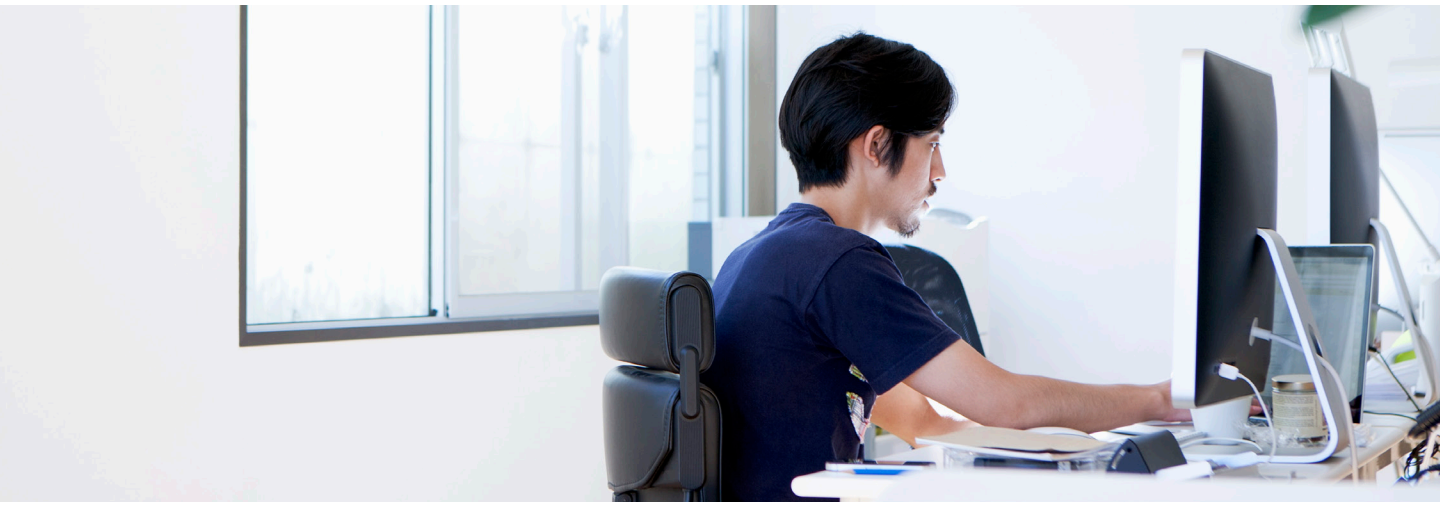
Introduction

In the world of medical devices – rules and regulations reign. Make sure your device complies with local requirements to help with the approval process and ensure people will have access to your potentially life-transforming technologies. Of course, these rules and regulations are ever-changing. That's why staying current is crucial; it can help expedite the process and mitigate delays.

If you plan to develop and commercialize a medical or *in vitro* diagnostic device in Europe, it's likely you've thought about the EU MDR. The EU MDR differs from the FDA Regulations in a few important ways, including classification and clinical testing.

Let's begin with a classification overview.



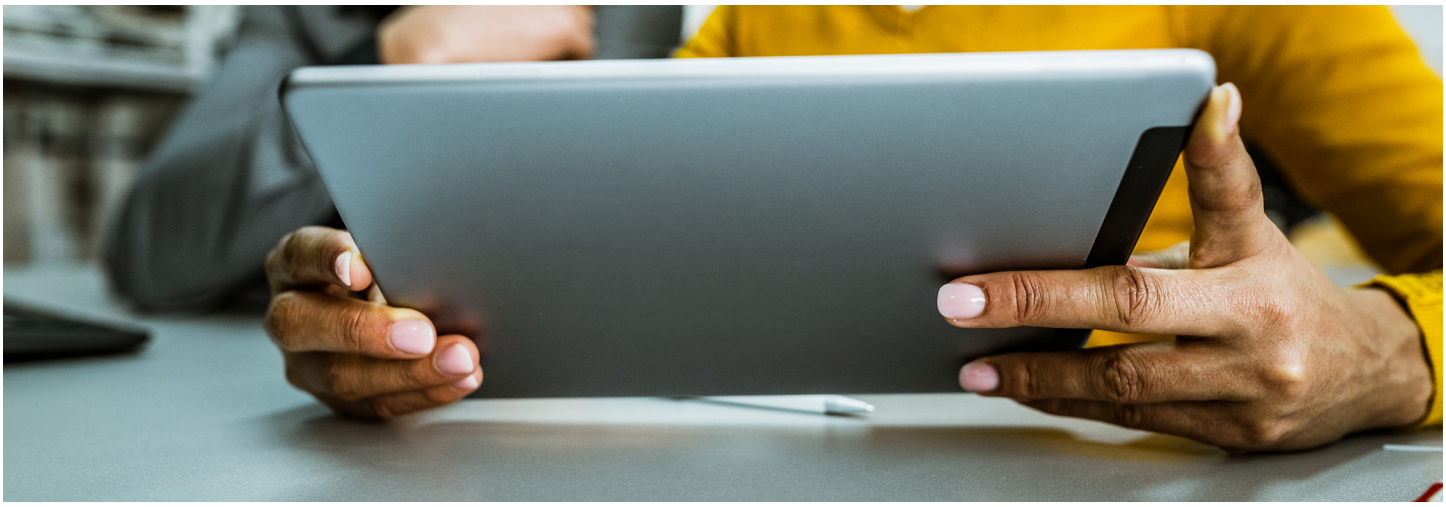
1 Chapter one: Regulating based on risk

How are devices classified?

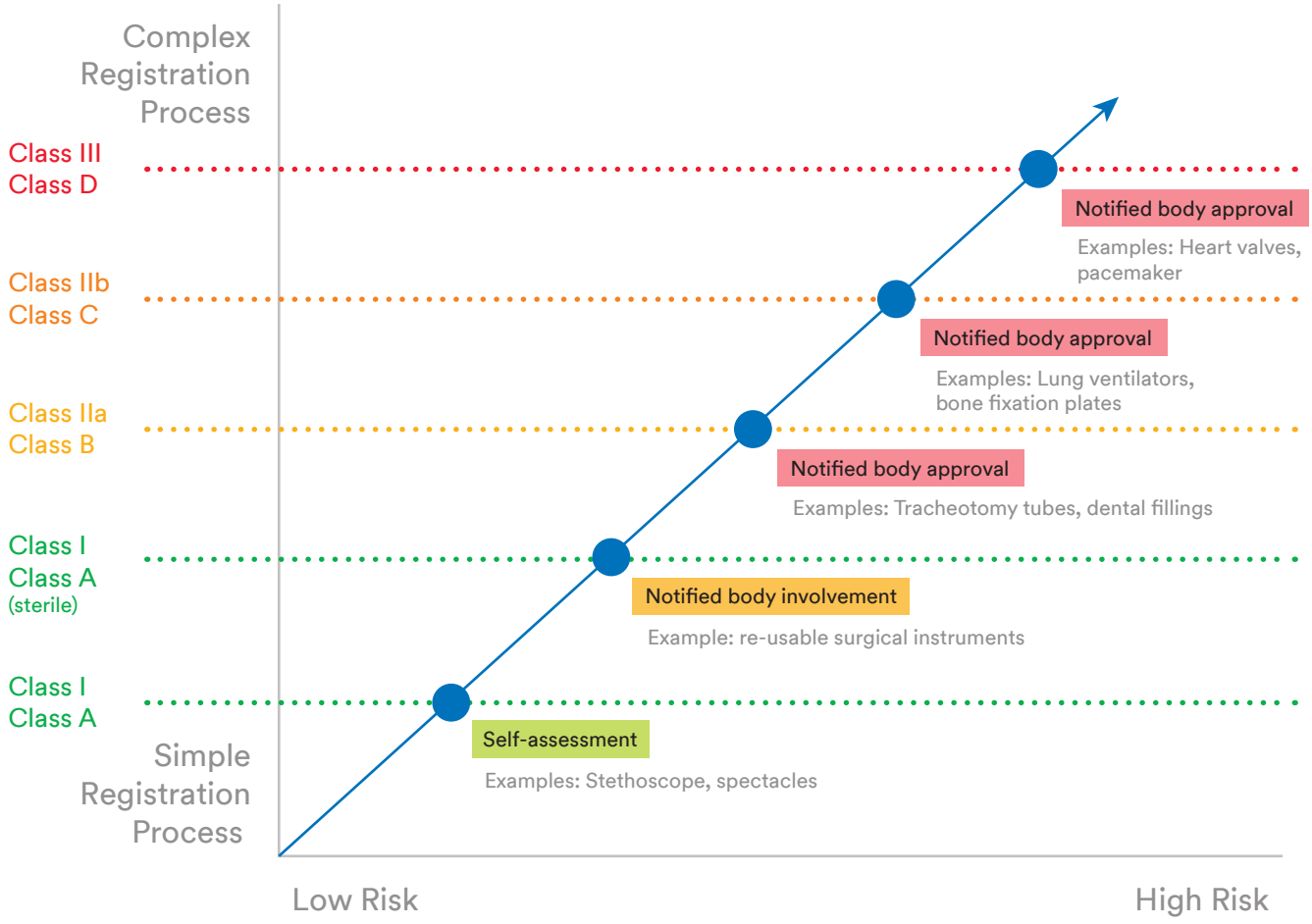
The EU MDR classifies medical and *in vitro* diagnostic devices based on risk. In this case, "risk" is defined as the combined likelihood and severity of harm caused by the device. In other words, what is the probability that harm will occur, and, if it does, how serious might it be?

The higher the individual or public health risk, the higher the classification. The higher the classification, the more notified bodies will monitor and apply rigorous requirements to the registration process.

Annex VIII of EU-MDR contains 22 rules for classification (Regulations). Application of the rules is governed by intended use of the device. The rules are based on the potential risks associated with the device and its technical design. Rules are broadly categorized in non-invasive devices (Rule 1 to 4), invasive devices (Rule 5 to 8), active devices (Rule 9 to 13). Devices not covered by these 13 rules are covered in the category for special devices (Rule 14 to 22).



Registering your device based on complexity and risk



EU MDR classifications:

Medical Device Classifications (Class I – III)
In vitro Diagnostics (Class A – D)

Who reviews the classifications?

The legal manufacturer of the device must determine device classification and submit documentation to the notified body for review. An example of a notified body is TÜV SÜD. If a notified body disagrees with the classification, the competent authority of a member state (e.g. in Ireland HPRA (Health Products Regulatory Authority)) will help resolve and define the classification.

What does the classification require?

When submitting the classification for review, a manufacturer must plan and share:

- The process for risk and quality management, technical documentation, as well as post-market surveillance and clinical follow-up during Medical Device/*In vitro* Device lifecycle
- How incidents will be recorded and reported, corrective actions, and how liability for harm caused by defective devices will be handled
- The point person responsible for regulatory compliance

An understanding of classification requirements is critical, because it helps manufacturers accurately plan for and expedite regulatory approvals. It's critical to comb through exceptions, too. Although each manufacturer must establish a quality management system (QMS), high-risk classifications require third-party QMS certification while low-risk classifications do not.

2 Chapter two: Partners and pitfalls

Partnering with suppliers

When it comes to EU MDR, the device manufacturer is expected to know and understand the substances in their medical device. The manufacturer must determine the threshold for labelling if limits are exceeded. That's why working with the right suppliers for the Medical Device/*In vitro* Device grade materials and articles is critical. The table below summarizes what a medical device manufacturer would want with respect to quality assurance from their suppliers to help navigate the EU MDR requirements.

Quality Assurance	MD/IVD Grade	Non-Regulated Grade
Quality system compliant with EU requirements	✓	✗
Avoidance of CMR*	✓	✗
Avoidance of EDC*	✓	✗
Not made with animal derived substances	✓	✗
Not made with natural rubber/latex	✓	✗
Change Management to GMP	✓	✗
Biocompatibility tested (ISO 10993)	✓	✗
Design control	✓	✗

*CMR – MDR Annex I, Section 10.4 – devices containing more than 0.1% of carcinogenic, mutagenic, reproductive toxicants (CMRs) and/or endocrine disrupting chemicals (EDCs) require review, justification and labelling

Potential pitfalls

If you're designing a device, it's likely you plan to commercialize. After all, you want to ensure your device reaches more people in more places and helps transform lives around the globe. Still, there are some red flags that often indicate a device will not be approved for mass production. Some potential pitfalls regarding the EU MDR include:

- No access to clinical data to support registration and no clinical benefit
- Re-certification of Medical Devices/*In vitro* Devices using components that are not medical grade
- Lack of Quality Management Control, change control and supplier management

3 Chapter three: The evolving nature of EU MDR

As rules and regulations change, it's important to remain aware of how these changes will affect your device. If your device has yet to go to market, take into account or be aware of these considerations during the development stage to plan accordingly.

Considerations

Implementation deadline for EU MDR/IVDR

The implementation deadline for EU MDR has changed to May 2021 for Class I medical devices but the implementation deadline for IVDR in May 2022 remains unchanged.

Existing materials and/or devices

Devices already in the market will require re-certification. Manufacturers must check their portfolio to determine what is required for re-certification.

Clinical equivalency

Devices need to be equivalent with respect to technical, biological and clinical properties, and the manufacturer must demonstrate access to equivalence data. Each EU Medical Device and *In vitro* Device requires supporting evidence of performance, safety, usability and clinical evaluation. Clinical studies need to demonstrate clinical benefit to patients in addition to safety and performance. When data demonstrating equivalence is not available, clinical investigation is required.

Unique Device Identifiers (UDIs)

Unique Device Identifiers enhance identification and traceability to EU Medical Devices and *In vitro* Devices. UDIs are a completely new feature of the regulation, and they consist of two parts: a device identifier specific to the device (UDI-DI) and a production identifier specific to the unit producing the device (UDI-PI). Manufacturers are responsible for adding and keeping up all necessary data in EUDAMED, which includes UDI information.

EU Medical Device accessories

Accessories for a medical device and for a product listed in Annex XVI will be classified separate from their respective device.

For a database of Notified Bodies, visit
New Approach Notified and Designated Organizations (NANDO).

Conclusion

It's normal to feel overwhelmed by rules and regulations. The good news? Choosing the right partners – from material suppliers to technical experts – can make EU MDRs easier to navigate. Most importantly, be sure to revisit rules regularly. Staying current and up to date will ensure you're on the right track and prepared to bring your life-changing devices to market.

3M experts are here to help as you design and develop your device!

Get in touch today.

Definitions:

The source of the definitions is the MHRA (Medicine & Healthcare products regulatory agency). The publication these are taken from is:
An introductory guide to the medical device regulation (MDR) and the in vitro diagnostic medical device regulation (IVDR), Mhra.gov.uk

Aesthetic products – Annex XVI of MDR lists out groups of products without an intended medical purpose, which will be regulated as medical device

Examples: non corrective contact lenses, equipment for liposuction, equipment intended for brain stimulation.

Borderline products – any product which could be both, either a medicine or a medical device. The regulatory authorities will decide which definition the product under consideration falls under.

Examples: medicated bandages, head lice products (medical device or medicinal product depending on their mode of action)

Eudamed – European database on medical devices. This is a central database where key information such as manufacturer, authorized representative and importer (if applicable) regarding medical devices has to be submitted

In vitro diagnostic medical device [IVD] – any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body.

Examples: pregnancy tests, blood glucose monitors

Medical device [MD] – any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by manufacturer to be used, alone or in combination, for human beings.

Examples: dental and surgical instruments, bandages and splints, treatment chairs and hospital beds.

Notified Body – A notified body is an organization designated by an EU member country to assess the conformity of a medical device/ *in vitro* diagnostic device with legal requirements.

Additional reading and resources:

IVDR – Regulation (EU) 2017/746 of the European parliament and of the council of 5 April 2017 on *in vitro* medical devices, and repealing Directive 98/79/EC and Commission decision 2010/227/EU

MDR – Regulation (EU) 2017/45 of the European parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directive 90/385/EEC and 93/42/EEC

Implementation Model for medical devices Regulation, Step by Step Guide; European Commission, ISBN: 978-92-79-89634-7 DOI: 10.2873/614436

Implementation Model for *in vitro* diagnostic medical devices Regulation, Step by Step Guide, European Commission, ISBN: 978-92-79-89124-3 DOI: 10.2873/41862

"Regulations." Official Journal of the European Union (2017): Annex VIII. Document.

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Medical Materials & Technologies
3M Center, Building 275-5W-05
St. Paul, MN 55144-1000 USA

Phone 800-584-2787
Web www.3M.com/MedTech

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