SOURCEINTELLIGENCE

EU MDR COMPLIANCE: A COMPLETE GUIDE

E-BOOK

Understanding and Complying with the EU Medical Device Regulation

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INTRODUCTION

The European Union (EU) Medical Device Regulation (MDR) (2017/745) is a regulatory framework that governs the production and distribution of medical devices in the EU. It holds medical device manufacturers to strict safety standards regarding the use of harmful substances in their devices. The regulation replaced the EU Medical Devices Directive (MDD) (93/42/EEC) and the Active Implantable Medical Devices Directive (AIMDD) (90/385/EEC).

Enacted in May 2021, the MDR is still in its implementation phase with various deadlines for distinct types of devices. It's critical for manufacturers and distributors of medical devices to understand the regulation, how their devices are classified, and how to achieve compliance before the MDD and AIMDD are phased out and the MDR is fully enforced.

In this e-book, we will explore:

- The basics of the EU Medical Device Regulation
- The classification of medical devices under the EU MDR
- Achieving EU MDR product compliance
- How Source Intelligence's EU MDR program can help

UNDERSTANDING THE EUROPEAN UNION MEDICAL DEVICE REGULATION

WHAT IS THE EU MEDICAL DEVICE REGULATION?

The European Union (EU) Medical Device Regulation (MDR) (2017/745) is a regulatory framework that governs the production and distribution of medical devices in the EU. It was adopted in 2017 and implemented on May 26, 2021, replacing the EU Medical Devices Directive (MDD) (93/42/EEC) and the Active Implantable Medical Devices Directive (AIMDD) (90/385/EEC). It intends to ensure that medical devices in the EU meet strict safety and quality standards while supporting fair market access.

The regulation restricts the use of certain hazardous substances in the design and manufacturing of medical devices and establishes reporting requirements for devices containing any restricted substances over a certain threshold. Medical device companies (i.e., legal manufacturers) that intend to sell or distribute their products within the EU member states must comply. [1]

WHICH SUBSTANCES ARE RESTRICTED BY THE EU MDR?

Under the EU MDR, medical devices cannot contain carcinogenic, mutagenic, toxic for reproduction, or endocrine-disrupting substances over the 0.1% (weight by weight) threshold without justification.

The definitions and reporting requirements for reportable substances under the MDR are consistent with the EU Classification, Labeling, and Packaging (CLP) regulation (1272/2008) [2] and the EU Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation (1907/2006) [3]. This means device manufacturers can review their suppliers' EU product safety data sheets (SDS) for data on any reportable components.

WHAT ARE THE IMPLEMENTATION TIMELINES FOR THE EU MDR?

Since the EU MDR is a relatively new regulation, there are implementation timelines for various device classifications. Devices previously determined to comply with the repealed directives (MDD and AIMDD) and issued compliance certificates are recognized as valid for the implementation period. This allows manufacturers to continue placing their devices on the market while transitioning to the MDR's reporting requirements.

The remaining implementation timelines for MDR compliance are as follows:

- **May 26, 2026** – Class III custom-made implantable devices.
- **December 31, 2027** – Class III devices covered by valid MDD/AIMDD certificates as of 3/20/2023 or Class IIb implantable devices (excluding well-established technologies (WET) under MDR, such as sutures, dental fillings, and screws).
- **December 31, 2028** – Devices covered by valid MDD/AIMDD certificates as of 3/20/2023, including Class IIb (excluding Class IIb implantable non-WET), Class IIa, Class I sterile devices, or Class I devices with a measuring function. This timeline also applies to devices that did not require notified body certification under the MDD, but now require it under the MDR. [4]

Although the final deadlines for transitioning to MDR compliance are a few years into the future, manufacturers and distributors of medical devices are strongly encouraged to take advantage of the time and submit their MDR applications as soon as possible to reduce the risk of disruptions.

WHAT IS THE DIFFERENCE BETWEEN THE EU MDR AND IVDR?

When the EU MDR was enacted in 2021, it was accompanied by a complimentary regulation, the In Vitro Diagnostic Medical Devices Regulation (IVDR) (2017/746). EU IVDR is similar to the EU MDR, but it is a separate regulation with several crucial differences:

- The IVDR covers in vitro devices only, and excludes any medical devices covered under the MDR.
- While the IVDR identifies the same harmful chemicals restricted under MDR, it does not restrict them.
- Compliance with the IVDR does not require chemical reporting, but device data is encouraged to be collected and used to support a company's internal product compliance due diligence efforts. [5]

CLASSIFICATION OF MEDICAL DEVICES UNDER EU MDR

The EU MDR's classification system is based on the level of risk posed to patient safety by the medical device. Here is a simple breakdown of the classification system:

- All medical devices under EU MDR are divided into four classes: I, IIa, IIb, and III.
- Of the four classes, class I devices, which pose the lowest risk to safety, are further separated into four sub-classes: Class I, Class Is, Class Im, and Class Ir.
- Each class covers devices in four categories: non-invasive devices, invasive devices, active devices, and devices with special rules.
- Each device category has its own classification rules to determine which class the device falls under.

DEVICE CLASSES

The device classes under EU MDR, their risk level, and examples of devices that fall within them are listed below.

Class I – Low-risk devices, such as bandages, glasses, and stethoscopes

Class I Sub-Classes:

- **Class I** – Non-sterile devices or products without a measurement function, like gauze or gel
- **Class Is** – Sterile product that must be transported in a sterile condition or sterilized on receipt, like a gown or a syringe
- **Class Im** – Devices with a measuring function, like syringes or spoons for administering medications
- **Class Ir** – Products that have been reprocessed or reused, like dental and surgical instruments

Class IIa – Medium-risk devices, such as hearing aids, surgical clamps, and catheters
Class IIb – Medium- to high-risk devices, such as ventilators, insulin pens, and long-term contact lenses
Class III – High-risk devices, such as pacemakers, prosthetic heart valves, and surgical mesh

DEVICE CATEGORIES

The device categories under EU MDR, along with each category's set of classification rules, are outlined below.

Non-Invasive Devices

Devices that do not enter the body, either through an opening or through the surface. Rules for non-invasives devices are as follows:

- **Rule 1** – All non-invasive devices fall under class I, unless one of the following rules (exceptions) applies:
- **Rule 2** – Devices used to channel or store blood, bodily liquids, cells, tissues, liquids, and gases
- **Rule 3** – Devices used to modify the biological or chemical composition of human tissues, cells, blood, and other bodily liquids
- **Rule 4** – Devices that come into contact with injured skin or mucous membrane

If any of these rules apply to a device, the device falls under one of the other three classes depending on the rule.

Invasive Devices

Devices that enter the body in whole or in part, either through an opening or through the surface. Invasive devices are defined by rules 5-8:

- **Rule 5** – Devices that enter the body through orifices
- **Rule 6** – Surgical devices for transient use
- **Rule 7** – Surgical devices for short-term use
- **Rule 8** – Surgical devices for long-term use and implantable devices

Invasive devices fall under each of the three classes depending on their applicability to the above rules.

Active Devices

Devices that require a source of energy to operate. Active devices are defined by rules 9-13:

- **Rule 9** – Therapeutic devices used to exchange or administer energy
- **Rule 10** – Devices used for diagnosis and monitoring
- **Rule 11** – Software that provides information used for making decisions with diagnosis or therapeutic purposes
- **Rule 12** – Devices used to administer and/or remove medicinal products, body liquids, or other substances
- **Rule 13** – All other active devices

Active devices not applicable to rules 9-12 are classified as class I. Active devices that do apply to rules 9-12 fall under one of the three other classes depending on the rule.

Devices with Special Rules

Combined devices or innovative technologies that fall under multiple categories under the regulation (a device that is both invasive and active, for example). Rules 14-22 apply to these special devices:

- **Rule 14** – Devices incorporating a medicinal substance
- **Rule 15** – Devices used for contraception or the prevention of sexually transmitted diseases
- **Rule 16** – Devices used for disinfecting, cleaning, and rinsing
- **Rule 17** – Devices used for recording diagnostic images generated by X-ray radiation
- **Rule 18** – Devices that are manufactured using non-viable tissues or cells from humans, animals, or their derivatives
- **Rule 19** – Devices incorporating or consisting of nanomaterial
- **Rule 20** – Invasive devices with respect to body orifices used for administering medicinal products by inhalation
- **Rule 21** – Devices composed of substances or combinations of substances that are introduced into the human body via an orifice or by skin application
- **Rule 22** – Active therapeutic devices with an integrated or incorporated diagnostic function that determines the patient management by the device

The classification of devices in this category depends on the device's primary purpose per the rules above. [1]

HOW TO CLASSIFY A MEDICAL DEVICE

Understanding the classifications of medical devices under the EU MDR is critical for compliance, as it enables you to easily identify which class your device(s) belong to and your reporting obligations. Once you understand the classifications and rules in the previous section, follow these three steps to classify your device(s):

1

Determine the right device category: non-invasive, invasive, active, or special.

2

Examine the classification rules within each category: rules 1-22. If multiple rules apply, adhere to the rule with the highest risk.

3

If your product falls under the Devices with Special Rules category, decide the primary purpose of the device to identify its classification based on rules 18-22.

ACHIEVING EU MDR PRODUCT COMPLIANCE

Achieving EU MDR product compliance requires a thorough understanding of the regulation and a solid framework for MDR-compliant systems and processes. The EU MDR compliance process can be simplified into three core areas:

1. The medical device
2. The clinical evidence portfolio
3. The regulatory systems, processes, and documentation

Medical Device

Medical devices must be well-designed and suitable for their intended purpose, show a positive benefit-risk profile, and follow all relevant General Safety and Performance Requirements (GSPRs) outlined in Annex I of the regulation.

Clinical Evidence Portfolio

All medical devices under the regulation must be accompanied by a clinical evidence portfolio that has been appropriately appraised and analyzed. Clinical evidence is defined as evidence generated and held by the manufacturer, as well as published data from independent journals and other sources.

Regulatory Systems, Processes, and Documentation

The EU MDR requires companies to supply more extensive data than the MDD. Required regulatory systems, processes, and documents for MDR compliance include:

1. Quality management systems
2. Post-market surveillance, which includes vigilance and post-market clinical follow-up
3. Risk management
4. Clinical evaluation
5. Technical documentation
6. A designated person responsible for regulatory compliance

ASSESSING COMPLIANCE

Compliance assessment under the MDR is based on the device's risk class. Notified Bodies must conduct the assessment for Class IIa, IIb, and III devices, but not for most Class I devices (except those that are sterile or have a measuring function). However, Class I compliance assessments must still be supported by the proper regulatory files, systems, and processes.

SUCCESSFUL COMPLIANCE

Successful compliance is shown with a CE (Conformité Européene) mark on the device. Most class I devices are self-declared, meaning manufacturers can apply the CE mark themselves after producing a declaration of conformity. A Notified Body must issue a certificate of conformity following a regulatory review before adding the CE mark for all other device classes. [1]

Figure 1: The Conformité Européene (CE) mark

STREAMLINE EU MDR COMPLIANCE OBLIGATIONS

Failing to meet EU MDR compliance obligations can lead to serious negative consequences, such as fines, litigation, product recalls, and reduced profitability. While EU MDR compliance is crucial, it is also complex. Understanding the classification of your product and collecting the right data is daunting, even if your products were compliant under the MDD. Partnering with a supply chain compliance company can help reduce the uncertainty around EU MDR compliance and streamline the compliance process.

SOURCE INTELLIGENCE'S EU MDR PROGRAM

Our EU MDR program facilitates supplier engagement, data analysis, and documentation generation through powerful compliance software with fully managed service options. Regardless of the level of support needed, we offer you peace of mind knowing that your medical devices follow the EU MDR.

With our EU MDR program, you will be able to:

Reduce internal resource burdens

Streamline due diligence efforts, such as supplier engagement, data collection, and report generation, and refocus internal resources on managing other parts of your business.

Minimize business risk

Easily provide documentation on demand. Your compliance data is housed in a centralized location, so you can efficiently generate reports and declarations to fulfill customer requests.

Gain supply chain visibility

Quickly identify issues with a complete view of your compliance and product data. Our configurable dashboards and BOM rollups display compliance verdicts for every part and component.

Increase risk foresight

Our regulatory experts guide our solution development, ensuring you have the right tools to anticipate changes to your compliance obligations and set you up for compliance success.

SCHEDULE A DEMO

Our team is here to help you achieve your EU MDR compliance goals. Whether you need a self-service or a fully managed program, database access, or expert consulting, we will guide you through every step. Schedule a demo to explore our EU MDR program, learn about our service options, and discover how simple EU MDR compliance can be.

Request a demo

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