**What does EU MDR mean?**

The EU MDR is the European Union Medical Device Regulation 2017/745 that were released in 2017 by the European Parliament and the Council of the European Union. The intent of the EU MDR regulations is to ensure a high standard of safety and quality for medical devices that are produced in, or supplied to, member countries of the European Union.

This regulatory framework is intended to better identify medical devices, as well as standardizing data and technological advances through an EU database (Eudamed). The regulation EU MDR is intended to be a regulatory framework for medical devices that can sustainably ensure health & safety while still encouraging innovation.

**What is MDD and MDR?**

The European Union Medical Device Directive (MDD) had been in place for almost 25 years before it was replaced by the new European Union Medical Device Regulation (MDR), issued in 2017. This previous directive constituted the EU framework for medical devices, but it did not include in vitro diagnostic medical devices.

However, it was determined that a fundamental revision of those directives was necessary to establish a more robust, transparent, sustainable, and predictable regulatory framework. The intent was to improve the overall level of health and safety of medical devices, while still supporting innovation in the industry.

**When was EU MDR published?**

While the council of April 4, 2017, on European medical devices was responsible for the creation of the new regulations, the EU MDR regulation was published on May 5, 2017. There is a three-year transition period for companies to comply with the new MDR EU regulation.

**When does EU MDR go into effect?**

While companies can start to comply with the new regulations immediately, the transition period from the EU MDD directive to the EU MDR regulations lasts for a four-year period and ends on 26 May 2021. After this date, any new medical devices will need to be certified to the new EU MDR regulations. Existing MDD-certified medical devices have an additional transition period until May 2024 to change their technical documentation to comply with the new MDR EU regulations.

**Which date must all existing MDD certified devices be certified under the MDR?**

The final date for all MDD-certified devices to be certified under the new MDR is May 25, 2024. If a medical device is compliant with the EU MDR regulations before this date, then it can be certified under the MDR, but it is not mandatory if its MDD certificate is still valid. If the MDD certificate expires before 25 May 2024, then such medical device needs to be recertified according to the MDR.

The last date to make this final certification according to the EU MDR is May 25, 2024 – after this date, all devices placed on the market must be certified under the EU Medical Device Regulation.

### What is EU MDR compliance?

The EU Medical Device Regulation has established a unique device identification (UDI) system that is similar to the United States Food and Drug Administration (FDA) system. If a company intends to provide or distribute medical devices into the EU marketplace, the labelling on those products will need to comply with this new UDI system. Compliance with the new MDR regulation is mandatory for medical device companies that intend to sell products in Europe.

### What is MDR certification?

MDR certification of a medical device verifies that the device meets all of the regulatory requirements for European Union medical devices; the certification is indicated by a CE Mark.

In order for medical devices to be certified, your company must implement a Quality Management System (QMS). Many companies use ISO 13485 as a way to implement this QMS, as this is the only QMS standard on the EU harmonized lists, and therefore it is the best way to implement the QMS as it relates to the MDR EU regulation.

### What are the EU MDR changes compared to MDD?

The European Union Medical Device Regulation (EU MDR) replaces the previous European Union Medical Device Directives (EU MDD). In particular, the new EU MDR (2017/745) amends previous directive 2001/83/EC and repeals council directives 90/385/EEC and 93/42/EEC.

**Table 1 - MDD v MDR Changes**

| Item that has changed | EU MDR | EU MDD |
|---|---|---|
| **Product classification** | New rules for substance-based devices<br><br>Devices with substances to be absorbed by the body are under a new classification system, causing many devices to be reclassified to higher-risk classes/<br><br>(MDR articles 1, 2, 22, 23, 51, 52) | Classification system for devices |
| **Clinical evaluation process** | Tighter areas of clinical investigations and post-market clinical follow up. Clinical evidence needs to be updated, clear, convincing, and publicly available. Clinical evaluations from implantable medical devices and Class III devices should be updated at least once per year.<br><br>(MDR articles 54, 55, 56, 61 to 82) | Clinical evaluation needs to take place. |

| Item that has changed | EU MDR | EU MDD |
|---|---|---|
| **Notified bodies** | Major change in supervision of notified bodies. Notified bodies will have more responsibilities, and some may lose their status as notified bodies.<br>(MDR articles 35 to50) | Included notified bodies: an organisation that is designated by an EU member state to do assessments of higher-class medical devices. |
| **Eudamed changes** | Eudamed database additions: post-market surveillance, safety and clinical performance, periodic safety updates, more clinical investigation data, and device registrations.<br>(MDR article 33) | Eudamed database founded in 2011, is a web-based platform storing regulator information. |
| **Economic operators** | Guidelines for assigning duties to importers, suppliers, subcontractors, assemblers, and EU representatives.<br>(MDR articles 10, 11, 13, 14, 30) | Not included |
| **UDI system** | The unique device identification aims to increase the traceability of MDR medical devices, especially reporting serious incidents and identification of counterfeit medical devices.<br>(MDR articles 18, 19, 27, 87) | Not included in the MDD |

**What is MDR and IVDR?**

The EU MDR regulations do not incorporate In Vitro Diagnostic Regulation (IVDR); this IVDR equipment is governed by a separate EU regulation 2017/746. However, Article 1 (point 7) of the MDR regulation clarifies the relationship between the IVDR regulation and the EU MDR regulation: if a device has both IVDR components and other medical device components, then the IVDR parts of any device are governed by the 2017/746 regulation, but the remainder of the device is covered by the MDR EU regulation.

In vitro medical devices are devices intended to be used for diagnostic, monitoring, or compatibility measurement of specimens outside of the human body. The new EU MDR regulations includes requirements for these types of products.

**MDR technical maps**

As has been the case with the EU MDD, all medical device products that have a CE mark need to have a technical file created, which proves that the device meets all the requirements of the EU directives for CE-marked products. Annex II of the new EU MDR includes revised requirements for what needs to be included in the contents, as well as the structure, or the technical file.

As per Annex II of EU MDR, the technical documentation needs to be clear, organized, readily searchable, and unambiguous. The elements to be include in the technical file are:

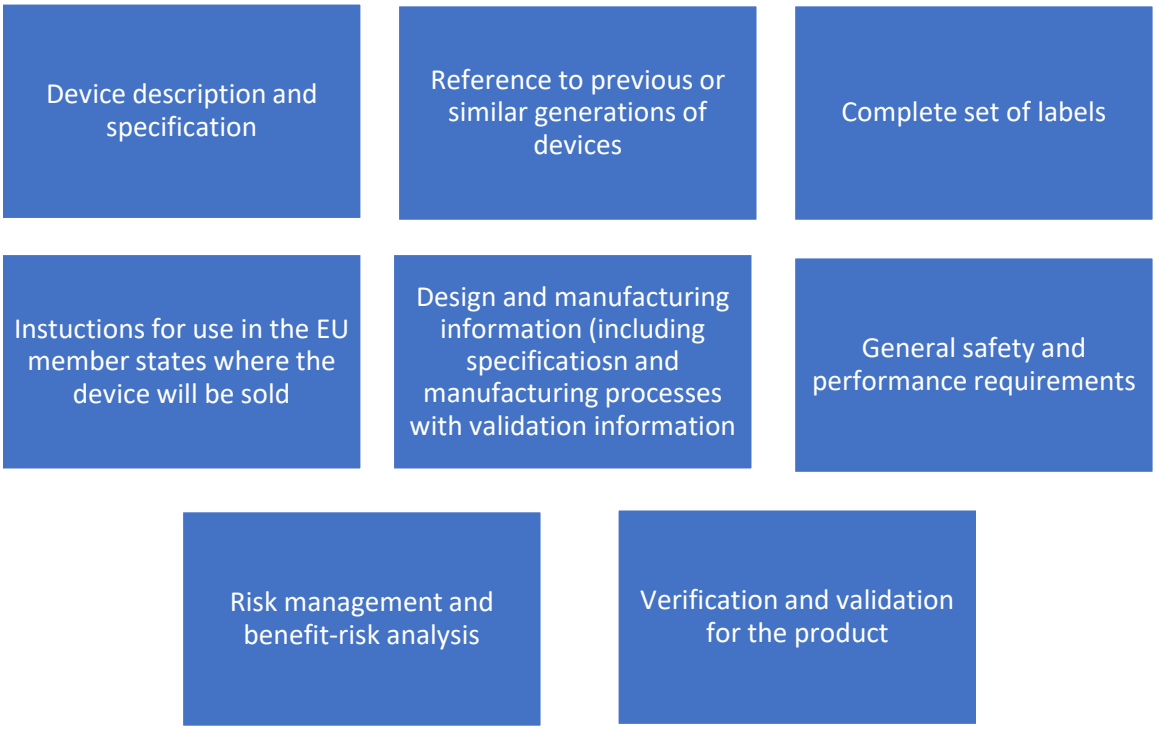


**Figure 1 - Contents of the Technical File**

This practice matches with ISO 13485:2016 clause 4.2.3, which requires the device manufacturers to create a technical file, or a medical device file.

**What are Class I medical devices?**

Class I medical devices are medical devices that are considered to be non-invasive, and include the following categories: sterile, measuring, or reusable surgical equipment. Some Class I devices can be self-certified, where Notified Body involvement is not required; however, you must still implement a QMS.

**What are examples of medical devices?**

The EU MDR regulations includes five classes of medical devices in Annex VIII. This annex classifies products according to 22 rules. Below is a short summary, with some examples of each:

**Class I (Low Risk)**: Non-sterile devices, or devices without a measurement function. These devices can be self-certified. For example: reusable surgical equipment (e.g., scalpel), stethoscopes, wheelchairs.

**Class I Special Function (Low/Medium Risk)**: Sterile devices, or devices with a measurement function. Non-invasive devices that do not meet the requirements of other classes, and invasive devices that are intended for transient use. For example: reprocessed devices, measurement devices, devices delivered sterile.

**Class IIa (Medium Risk)**: Invasive devices intended for short-term use. For example: tooth implants, tracheotomy tubes, syringe, X-ray device.

**Class IIb (Medium/High Risk)**: Invasive devices intended for long-term use. For example: implantable birth control, blood bags.

**Class III (High Risk)**: Implantable medical devices intended for long-term use. For example: pacemakers, breast implants, spinal disc implants, drug-coated stents.