**The MDR 2017/745**

The European Medical Device Regulation (MDR) is a new set of regulations that governs the production and distribution of medical devices in Europe, and compliance with the regulation is mandatory for medical device companies that want to sell their products in the European Union. The European Medical Device Regulation (MDR), which was adopted in April 2017, changes the European legal framework for medical devices and introduces new principal and supportive responsibilities for EMA and for national competent authorities in the assessment of certain categories of products. The Regulation entered into force in May 2017 and had a staggered transitional period. The MDR replaces the existing Directives for medical devices (93/42/EEC and 90/385/EEC). The Regulation on in vitro diagnostic medical devices, which also came into force in May 2017, replaced Directive 98/79/EC when it came into application on 26 May 2022.

If your company was already compliant with the Medical Devices Directive (MDD), you may want to update this as the MDR represents brand new regulations with a lot of changes.

**What is our role as Requalite in the process?**

As an independent medical device Regulatory and Quality Consulting company, we offer consultation to MD manufacturers for the **planning, preparation, execution, and reporting of clinical evaluations** for existing as well as novel MDs to ensure compliance with MDR and a smooth placement on the market. Requalite prides itself with providing the very best services for **planning, writing, and documentation of clinical evaluations and reports** provisioned in the MDR. This includes:

- **Clinical Evaluation Plan (CEP)**
- **Clinical Evaluation Report (CER)**
- **Performance Evaluation Plan (PEP)**
- **Performance Evaluation Report (PER)**
- **Literature Search Plan (LSP)**
- **Literature Search Report (LSR)**
- **Analytical Performance Report (APR)**
- **Clinical Performance Report (CPR)**
- **State of the Art (SOTA)**
- **Post-market Surveillance (PMS) Plan**
- **Post-market Surveillance (PMS) Report**
- **Periodic Safety Update Report (PSUR)**
- **Post-market Performance Follow-up (PMPF) Plan**
- **Post-market Performance Follow-up (PMPF) Report**
- **QMS in accordance with ISO13485**
- **RMS in accordance with ISO14971**

We also provide resources for the manufacturers to help them with **navigation in the system, stay updated with changes** in the regulation, and **training** for their personnel responsible for regulatory compliance. Requalite is proud to be house of expert Medical Writers with strong scientific

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background in Medical Device fields.

**Key dates for MDD-MDR transition:**

26 May 2017: Devices that conform with the MDR may be placed on the market

Until 25 May 2021: All certificates issued under medical devices Directives (AIMDD/MDD) are valid until their date of expiry

26 May 2021-25 May 2024: Certificates issued under the AIMDD/MDD before the MDR fully applies may remain valid until 25 May 2024 under certain conditions

From May 2024: All devices placed on the market must be in conformity with the MDR

26 May 2024-27 May 2025: MDD devices which were already placed on the market may continue to be made available

**What are the key changes from MDD to MDR?**

Compared with its predecessor, the MDD, the new European MDR is less focused on the pre-approval stage of medical device manufacturing, and instead, promotes a lifecycle approach to medical device regulation.

While the old MDD essentially served as a manual for how medical device companies could get their CE marking and get to market, the new regulations encourage policies and procedures that elevate the responsibilities of medical device companies for their products throughout the entire product lifecycle.

***A great reset*** is provisioned with the transition from MDD to MDR, where all currently approved MDs (under MDD) must be recertified for the new requirements (under MDR) during the transition period.
***Product coverage*** is expanded in MDR to include some devices that have no intended medical purposes (i.e., cosmetic implant devices and materials, colored contact lenses, etc.).
***Device classification*** is based on risk, duration of contact with body, and invasiveness. Risk classes range from Class I (low risk MDs) to Class III (high risk MDs) where higher risk classes are subject to higher clinical standards and regular post-market scrutiny.
***Common specifications (CSs)*** will be provisioned by expert panels at the request of the European Commission (EC). Manufacturers and NBs will be required to take these CSs when designing, developing, manufacturing, and assessing MDs for the EU market.
***Clinical evidence*** provided by the manufacturers is required to rigorously demonstrate clinical performance and safety of the MD. Level of evidence is based the MD's assigned risk class. Class IIA and Class IIB MDs are subject to systematic clinical evaluation.
***Post-market surveillance*** is to be conducted by the manufacturer in order to assess and report safety risks periodically. The process will also include unannounced audits, product sample checks, product tests, and annual safety reporting.

***Traceability*** of any device is a requirement (through a unique device identification - UDI) for better traceability, assessment, and recall of flawed devices.
***A qualified person responsible for regulatory compliance*** of the MD is to be assigned by the manufacturer. There is scientific uncertainty about the risks and benefits of nanomaterials used for devices. In order to ensure a high level of health protection, free movement of goods and legal certainty for manufacturers, it is necessary to
introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU (4), with the necessary flexibility to adapt that definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of devices, manufacturers should take special care when using nanoparticles for which there is a high or medium potential for internal exposure. Such devices should be subject to the most stringent conformity assessment procedures. In preparation of
implementing acts regulating the practical and uniform application of the corresponding requirements laid down in this Regulation, the relevant scientific opinions of the relevant scientific committees should be taken into account.

**What devices are covered under the MDR?**

The MDR defines the term "medical device" as an "instrument, apparatus, appliance, software, implant, reagent, material, or other article" that is used for any of the following:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease, disability, or injury, but not for disability or injury prevention
- Investigation, replacement, or modification of an anatomical, physiological, or pathological process
- Providing data via in-vitro examination of samples derived from a human body

This definition covers a broad range of existing devices, but that's not all. The MDR newly specifies certain types of products that need to obtain a CE marking, including products used to clean, disinfect, or sterilize medical devices, and devices used to control and support conception, whether through pharmacological, immunological, or metabolic means.

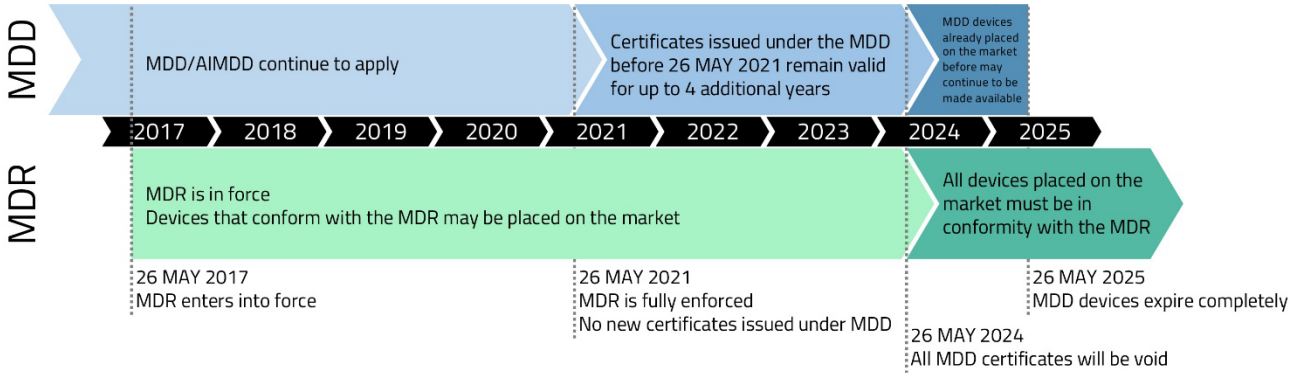


Figure 1 showing MDD to MDR transition