



MALTA

MEDICINES  
AUTHORITY

# Factsheet for Authorised Representatives of Medical Devices



*This fact sheet is intended primarily for authorised representatives of medical devices and in vitro diagnostic medical devices.*

## Introduction to Medical Devices Regulations

### EU Regulations

The Medical Device Regulations (MDR) and In Vitro Diagnostic Regulations (IVDR) were established by the European Parliament and council on medical devices on the 5<sup>th</sup> of April 2017.

The new [Medical Devices Regulation \(EU\) 2017/745](#) and the [In Vitro Diagnostic Medical Devices Regulation \(EU\) 2017/746](#) bring EU legislation in line with technical advances, changes in medical science and progress in law-making. These regulations enhance clinical safety and create fair market access for manufacturers and healthcare professionals by creating robust, transparent, and sustainable regulatory frameworks which are recognised internationally.

### Maltese Law

The Maltese legislation consists of the following:

- [‘In Vitro Diagnostic Medical Devices Regulations’ \(S.L. 427.16\) and LN 318 of 2020 ‘In Vitro Diagnostic Medical Devices \(Amendment\) Regulations’](#)
- [LN 321 of 2020 ‘Medical Devices and In-Vitro Diagnostic Medical Devices Provision on the Maltese Market Regulations’](#)

Medical devices and all accompanying information must be in one of the national languages of Malta; English and Maltese, or both.

## What happened on the 26<sup>th</sup> of May 2021?

The date of application of the Medical Device Regulation (MDR) was the 26<sup>th</sup> May 2021. The transition period for the MDR therefore ended on this date. The corresponding date of application of the In Vitro Diagnostic Medical Devices Regulation (IVDR) is set for the 26<sup>th</sup> May 2022.

Maltese legislation is enforced in parallel to the MDR. It is obligatory for all Economic Operators (EO) of medical devices to comply with the MDR. All EOs are required to be fully aware of the new requirements and enforce the new regulations.



# What type of Economic Operator am I?

As per Article 2 (35) of the MDR, the term 'Economic Operator' refers to 'a manufacturer, an authorized representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3)'.

It is important to identify the role/s of your organisation as per the MDR.

**Authorised Representative:** Any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under the MDR.

## What are my obligations?

It is important for authorised representatives to ensure that they have appropriate resources, processes and systems in place to fulfil their obligations under the new Regulations. Below are some of the key obligations under the MDR. Article 11 of the MDR denotes the majority of the obligations.

### Authorised Representative

- Must be located within an EU Member State
- Possess a Mandate with the Manufacturer/s they represent clearly defining responsibilities and tasks as agreed upon with the manufacturer
- Establish a Quality Management System
- Verify:
  - ❖ EU Declaration of Conformity and technical documentation have been drawn up
  - ❖ A copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate is kept
  - ❖ UDI is assigned
  - ❖ Devices are registered in EUDAMED
- Cooperate with the competent authorities on any preventive or corrective action taken to eliminate or mitigate the risks posed by devices
- Immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents
- Have a permanently available Person Responsible for Regulatory Compliance (PRRC)
- Keep available a copy of all relevant documentation for 10 years (or 15 years in the case of implantable devices)
- Register as an actor in EUDAMED
- Authorised Representatives having their registered place of business in Malta must register as an Authorised Representative with the Malta Medicines Authority

# What applications forms apply to me?

The following application forms, which are applicable to authorized representatives, may be found on the [Malta Medicines Authority website](#):

**MT-MDF-01** - Application Form for Certificates of Free Sale (CFS) for Medical Devices

**MT-MDF-02** - Application Form for Organisation Registration in relation to Medical Devices

**MT-MDF-03** - Application Form for Medical Device Registration for Medical Devices Placed on the EU Market

Guidelines related to application forms and fees are available on the [Malta Medicines Authority website](#).



## Timelines

As of the 26<sup>th</sup> May 2021, all new medical devices must comply with the MDR. Certificates issued under the Directives are valid until their expiration date or up to 27<sup>th</sup> May 2024; whichever comes first. From the 26<sup>th</sup> of May 2021, devices previously certified under the Directives must comply with the requirements of the MDR relating to post-market surveillance, vigilance, as well as the registration of economic operators and devices, as per Article 120 (3).

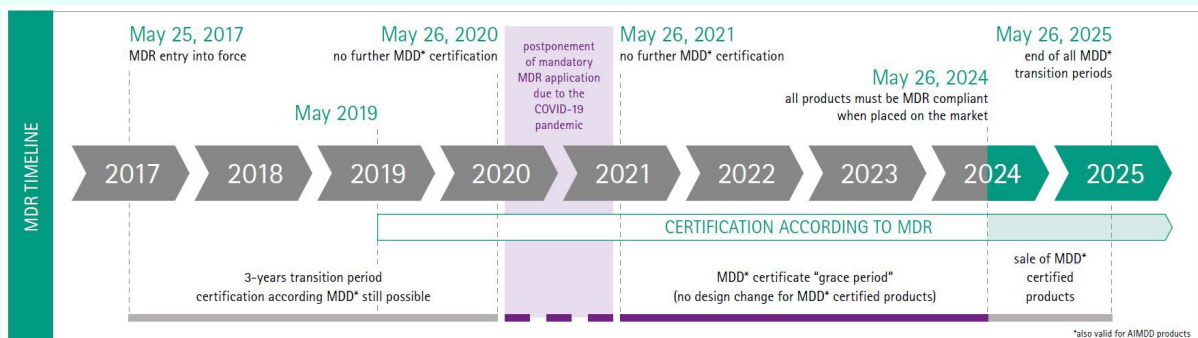


Figure 1: Timetable for the implementation of the MDR

## More information

For more information on any of the above topics, please refer to the Medical Devices section on the [Malta Medicines Authority website](#).

Specific queries related to medical devices can be submitted to [devices.medicinesauthority@gov.mt](mailto:devices.medicinesauthority@gov.mt)