MALTA MEDICINES AUTHORITY

Factsheet for

Manufacturers

of Medical Devices

This fact sheet is intended primarily for manufacturers 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 5th 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 26th of May 2021?

The date of application of the Medical Device Regulation (MDR) was the 26th 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 26th 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.

Manufacturer: A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

What are my obligations?

It is important for manufacturers 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 10 of the MDR denotes the majority of the obligations.

Manufacturer

- Establish a Quality Management System
- Establish a Risk management system
- Carry out clinical evaluation and Post-Market Clinical Follow-up (PMCF)
- Draw up and keep up to date technical documentation, including a Declaration of Conformity, and affix the CE marking of Conformity, following demonstration of compliance with the applicable conformity assessment procedure
- Assign a Unique Device Identifier (UDI)
- Register medical devices appropriately
- Ensure labelling & language requirements are fulfilled
- Implement and keep up to date a Post-Market Surveillance system as per Article 83 of the MDR
- Inform the National Competent Authority (NCA) of any devices presenting serious risk, including information related to the non-compliance of the device and any corrective actions taken
- Establish a system for recording and reporting incidents and Field Safety Corrective Actions (FSCA)
- Fulfil periodic and trend reporting requirements
- Establish a recall system
- Have measures in place to provide sufficient financial cover for damage compensation
- Appoint a Person Responsible for Regulatory Compliance (PRRC) who is permanently available
- Retain all relevant documentation for 10 years (or 15 years in the case of implantable devices)
- Register as an actor in EUDAMED
- Manufactures having their registered place of business in Malta must register as a manufacturer with the Malta Medicines Authority

What application forms apply to me?

The following application forms, which are applicable to manufacturers, 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 26th 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 27th May 2024; whichever comes first. From the 26th 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).

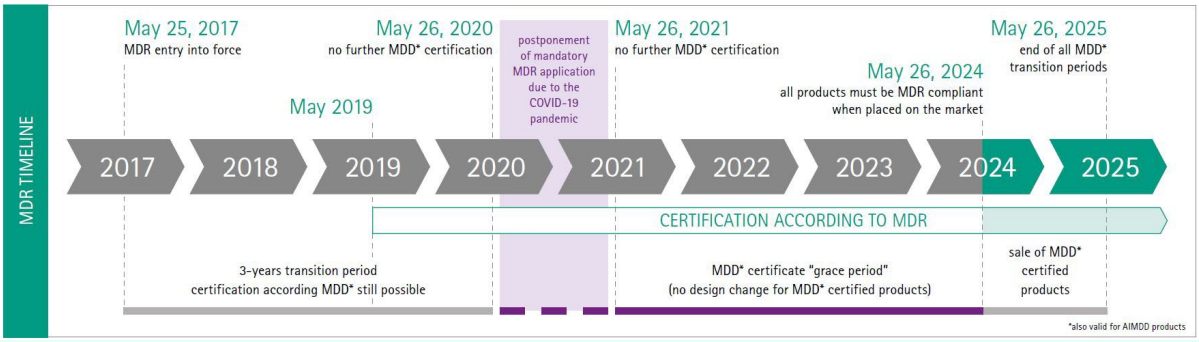

Figure 1: Timetable for the implementation of the MDR

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**