MALTA MEDICINES AUTHORITY

Factsheet for

Importers & Distributors of Medical Devices

This factsheet is intended primarily for importers and distributors 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.

Importer or Distributor?

Importer

Any natural or legal person established within the Union that places a device from a third country on the Union market. The importer shall place on the Union market only devices that are in conformity with Article 13 of the Regulations.

This means that if your organisation sources medical devices directly from third countries, this is seen as an act of importation. This includes the United Kingdom, following Brexit.

Distributor

Any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service as defined in Article 14 of the Regulations.

This means that your organisation sources its medical devices solely from other EU Member States.

What are my obligations?

It is important for importers and distributors to ensure that they have appropriate resources, processes and systems in place to fulfil their obligations under the new Regulations. Below are some key obligations under the MDR.

Importer

- Verify:
  - ❖ CE mark & Declaration of Conformity are valid
  - ❖ IFU & Labelling requirements are met
  - ❖ Manufacturer is identified & AR is designated
  - ❖ UDI is assigned
  - ❖ Devices are registered in EUDAMED
- Keep a copy of the Declaration of Conformity and any relevant certificates
- Include contact details on packaging as per article 13(3)
- Inform the National Competent Authority (NCA) of devices presenting serious risk and potentially falsified devices
- Ensure storage and transport conditions comply with those set by the manufacturer
- Keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and provide relevant EOs with information requested by them
- Cooperate with Manufacturer/AR and NCA on corrective actions, withdrawals and recalls
- Register as an actor in EUDAMED
- Register as an importer with Malta Medicines Authority

Distributor

- Verify:
  - ❖ CE mark & Declaration of Conformity are valid
  - ❖ IFU & Labelling requirements are met
  - ❖ Importer is identified
  - ❖ UDI is assigned
- Inform the NCA of devices presenting serious risk and potentially falsified devices
- Ensure storage and transport conditions comply with those set by the manufacturer
- Keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and provide relevant EOs with information requested by them
- Cooperate with Manufacturer/AR, importer and NCA on corrective actions, withdrawals and recalls
- Register as a distributor with Malta Medicines Authority

What application forms apply to me?

The following application form, which is applicable to importers and distributors, may be found on the Malta Medicines Authority website:

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

This application form is used to register an economic operator with the Malta Medicines Authority in order to increase visibility and traceability and to enable efficient communication between both parties.

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).

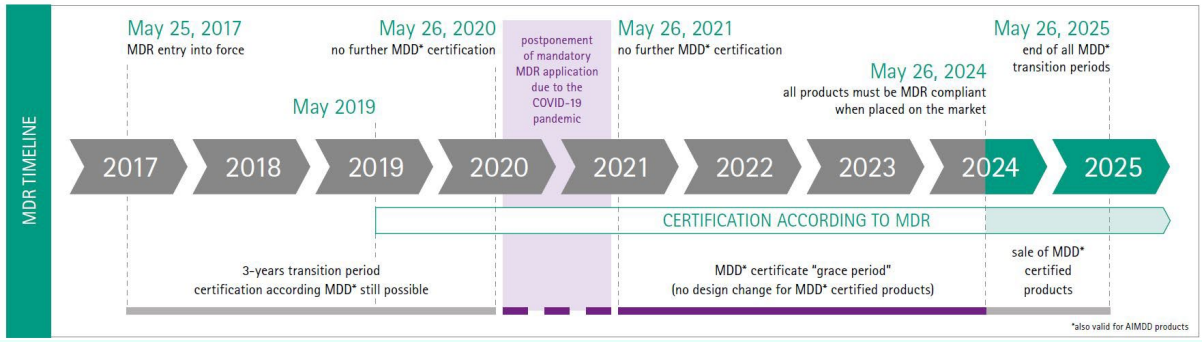

Figure 1: Timetable for the implementation of the MDR

What systems do I need to have in place?

Good Distribution Practice (GDP)

Distributors and importers shall ensure that they operate under GDP conditions, as per the Guidance Document issued by the Malta Medicines Authority. Storage sites do not need to be listed under a Wholesale Dealer's License.

GDP Requirements

The following are the minimum standards that importers and distributors must meet:

- Appoint a Medical Device Registered Person (MDRP)
- Operate an effective Quality Management System (QMS)
- Have appropriate premises and equipment
- Have qualified and trained personnel
- Have a pest control system in place
- Have adequate product handling and inventory control systems
- Have a Record Keeping system to ensure traceability

Quality Management System (QMS)

Distributors and importers shall ensure that they have an effective quality management system in place. The quality management system shall cover, among other things, procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question, in order to respond to safety issues, or to bring the device in conformity with the Regulations.

QMS Requirements

The following are the minimum requirements in a QMS:

- Documentation system
- Training of personnel
- Complaints handling system
- Disposal of goods/ Returns management system
- Recall procedure

Relabelling

Labelling of medical devices must be in English or Maltese to be placed on the Maltese market. Any relabelling or repackaging of a medical device, as stated in article 16(2) of the MDR, must be communicated with the manufacturer and the Malta Medicines Authority at least 28 days prior to making the relabelled or repackaged device available on the market. Upon request, a sample or mock-up of the relabelled or repackaged device, including any translated label and instruction for use, must be made available to the manufacturer and Malta Medicines Authority by the distributor or importer.

Within the same period of 28 days, the distributor or importer shall submit to the Malta Medicines Authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned article 16(2), demonstrating that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.

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**