MALTA MEDICINES AUTHORITY

Guidance for Application for Organisation Registration in relation to Medical Devices

1. Introduction

The application form for organisation registration is being presented by the Malta Medicines Authority to increase functionality at all regulatory levels and to allow courteous communication between distributors, importers, manufacturers, authorised representatives, notified bodies and the National Competent Authority.

Any further clarification on this guidance document may be obtained from Malta Medicines Authority, by sending an email to *mdforms.medicinesauthority@gov.mt.*

2. Scope

The purpose of this guidance document is to provide comprehensive instructions to the user when registering the organisation with the National Competent Authority. This guidance document is intended to offer a robust approach towards the proficiency and control of how the user must accurately complete and submit the registration form.

3. Terms, Definitions and Abbreviations

Authorised Representative

Authorised representative means 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 regards to the latter's obligations under this Regulation. [Regulation (EU) 2017/745 Article 2(32) & Regulation (EU) 2017/746 Article 2(25)]

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.

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 (EU) 2017/745 & (EU) 2017/746.

In Vitro diagnostic medical device

any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

a) concerning a physiological or pathological process or state;
b) concerning congenital physical or mental impairments;
c) concerning the predisposition to a medical condition or a disease;
d) to determine the safety and compatibility with potential recipients;

e) to predict treatment response or reactions;
f) to define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices; [Regulation (EU) 2017/746 Article 2(2)]

Manufacturer

Manufacturer means 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. [Regulation (EU) 2017/745 Article 2(30) & Regulation (EU) 2017/746 Article 2(23)]

Medical Device

Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

[Regulation (EU) 2017/745 Article 2(1)]

Note: The term 'medical device' in this guidance document also refers to in-vitro diagnostic medical device.

Medical Device Registered Person (MDRP)

A person appointed by an economic operator who is responsible for ensuring regulatory compliance of medical devices placed on the Maltese market. This person must be registered with the Malta Medicines Authority.

Person Responsible for Regulatory Compliance (PRRC)

A person with regulatory expertise who is appointed by a manufacturer or authorised representative to ensure regulatory compliance of medical devices with EU Regulations, at least ensuring that:

(a) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;
(b) the technical documentation and the EU declaration of conformity are drawn up and kept up to date;
(c) the post-market surveillance obligations;
(d) the reporting obligations;
(e) in the case of investigational devices, as per Regulations.
[Regulation (EU) 2017/745 Article 15 & Regulation (EU) 2017/746 Article 15]

Single Registration Number (SRN)
Generated by EUDAMED and issued by the Competent Authority after validating the registrations request. [Regulation (EU) 2017/745 Article 31(2) & Regulation (EU) 2017/746 Article 28(2)]

Third Party Logistics (3PL)
Any natural or legal person, other than the legal owner of devices, which takes part in Storage and/or Transportation activities of said devices. [MDCG 2021/27 Rev.1]

4. Specific Guidance

4.1 Applicants applying through the Organisation Registration Form
The application form for an organisation registration may be requested by a manufacturer, authorised representative, importer, distributor and a notified body in relation to medical devices. The applicants requesting the application may be first time users or registered users who aspire to make further amendments in the details of the originally submitted application form at the National Competent Authority.

4.2 General Details related to Applying

4.2.1 Application Form Title
The application form related to this guidance document is *MT-MDF02 - Application Form for Organisation Registration in relation to Medical Devices*, which may be accessed from the Malta Medicines Authority website https://medicinesauthority.gov.mt, under the section for medical devices.

4.2.2 Application Form
The registration is a fillable form which must be filled in electronically using the grey-shaded areas. Handwritten application forms will not be accepted. A signed scanned copy of the completed form and supporting documentation must besubmitted to the Malta Medicines Authority via email on mdforms.medicinesauthority@gov.mt.

4.2.3 Acknowledgment
Once the application form has been received an acknowledgment will be sent. Upon successful review, a unique organisation registration number will be forwarded to the applicant.

4.2.4 Official Languages

The official languages in Malta are Maltese and English. All application forms and supporting documentation for the registration process must be completed in either Maltese or English.

4.3 Filling in the Application Form

All sections must be completed.

The Application Form is divided as follows:

- Section A: Application Introduction
- Section B: Organisation Details
- Section C: Details of Payment
- Data Protection Consent Statement
- Additional documentation
- Malta Medicines Authority Declaration for Form Submission

4.3.1 Section A: Application Introduction

This is divided into two sections:

4.3.1.1 Date of Application and applicant details

The date of application for the application form for organisation registration will be completed automatically. The individual completing the application shall provide their name, surname, email address contact number and their role in the organisation.

4.3.1.2 Type of Application

The applicant shall choose as applicable, to clearly indicate the type of application that will be submitted to the National Competent Authority. In the case where the applicant will be submitting an amendment / withdrawal application, it is of crucial importance that the applicant quotes the organisation's registration number which the Malta Medicines Authority had already provided to the user upon original submission.

4.3.2 <u>Section B: Organisation Details</u>

The details of the organisation which will be registering its medical devices should be included here.

4.3.2.1 Organisation Type

The organisation type of the entity being registered with the National Competent Authority shall be indicated. *Section 3 – Definitions* of this guidance document may be used as a reference.

4.3.2.2 Organisation Contact Details

The applicant shall input the Organisation Name, Organisation Telephone Number, Legal Registered Address, Operational Address, Warehouse Address(es) including sub-contracted warehouses. Organisation Email address, Contact Name, job title, telephone number and Email address of the organisation contact person and Malta Business Register Number (MBR). The MBR number is not applicable for sole traders. Where applicable the organisation contact details shall correspond with the Malta Business Register details. If the applicant is a

Manufacturer, Authorised Representative or Importer, the EUDAMED SRN shall be inputted. If the applicant is a manufacturer or an authorised representative, the PRRC's contact details must be listed. If the applicant is a distributor or importer, the MDRP's contact details, together with the MDRP registration number, must be provided. It is the responsibility of the organisation to update the Authority of any changes in these contact details.

4.3.3 Section C: Details of Payment

Refer to the *GL-MDF07 Guidance on fees in relation to Medical Devices* available on the Malta Medicines Authority website https://medicinesauthority.gov.mt, under the section for medical devices. The applicant is to select whether standard or fast track service is required, and relevant proof of payment must be attached.

4.3.3.1 Service

Upon submission of all relevant documentation, a standard processing timeframe of 30 working days commences.

- Standard Service

Standard processing timeframe from receipt of the application form at Malta Medicines Authority.

- Fast track Service

Fast track processing of 10 working days from receipt of the application form at Malta Medicines Authority.

Should the Authority require any further information or clarification, this will be communicated to the applicant. A stop-clock will be initiated, for both standard and fast track service, and restarted upon receipt of responses. If further queries arise or responses are not satisfactory, the applicant is informed, and clock stops/starts accordingly with the cycle repeating itself.

4.3.3.2 Proof of Payment

This document will be verified by the Finance & Corporate Services Unit at the Malta Medicines Authority, confirming receipt of funds.

4.3.4 Data Protection Consent Statement

Applicant shall confirm consent, by ticking the box in this section, to the processing of personal data by the Malta Medicines Authority and understands that this data shall be processed in accordance with the General Data Protection Regulation (GDPR).

4.3.5 Malta Medicines Authority Declaration for Form Submission

Applicant shall sign the Malta Medicines Authority declaration that all the information submitted within this registration form is correct and complete.

4.4 Documents Required

The documents to be submitted with this Application Form are:

- Malta Business Registry Certificate of Company Registration (softcopy)
- Proof of payment (softcopy)
- I.D card of the representative person of the organisation (softcopy)
- Medical Device Registered Person official documentation (softcopy, if applicable)
- Notarised copy of the letter of designation between the manufacturer and the European authorised representative (softcopy, if applicable)

Any additional documents relevant to the function of the organisation must be made available to the Malta Medicines Authority, upon request.

For an application to be considered, all sections must be filled in completely and accurately as per this guidance document. Sections not applicable to your organisation must be filled in with N/A

5. References

Cap 458 Act no VII of 2020, An Act to amend the Medicines Act https://legislation.mt/eli/act/2020/7/eng

S.L. 458.59 Medical Devices and In-Vitro Diagnostic Medical Devices Provision On The Maltese Market Regulations
https://legislation.mt/eli/sl/458.59/eng

Legal Notice 254 of 2025 Medicines Act (Cap. 458) - Various Laws relating to Fees in respect of Private Medical Premises and Medicines (Amendment) Regulations, 2025
https://legislation.mt/eli/ln/2025/254/eng

EU legislations- Medical Devices Regulation (EU) 2017/745 and In-Vitro Diagnostic Medical Devices Regulation (EU) 2017/746
https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

Signatures on file

List of Appendices

N/A