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

Where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorised representative. The authorised representative plays a pivotal role in ensuring the compliance of the devices produced by those manufacturers and in serving as their contact person established in the Union. The authorised representative should be jointly and severally liable with the importer and the manufacturer. The authorised representative is legally liable for defective devices in the event that a manufacturer established outside the Union has not complied with its general obligations.

Conformity Assessment Body

A body that performs third-party conformity assessment activities including calibration, testing, certification and inspection. [Regulations (EU) 2017/745 & (EU) 2017/746]

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.

Manufacturer

A natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under its own name, regardless of whether these operations are carried out by those persons themselves or on their behalf by a third party.

Medical Device

Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

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

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.

Notified Body

A Conformity Assessment Body (CAB) designated in accordance with Regulations (EU) 2017/745 & (EU) 2017/746.

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.

e-form: Electronic Form

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 registration 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 E-Form

The registration is an e-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 e-form and supporting documentation must be uploaded.

4.2.3 Acknowledgment

Once the registration 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 Registration Form

All sections must be completed.

The Registration Form is divided as follows:

- Section A: Application Introduction
- Section B: Organisation Details
- Section C: Details of Payment
- Data Protection Consent Statement
- 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 and contact number.

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 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 Section B: Organisation Details

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

4.3.2.1 Organisation Status

The organisational status 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 organisation contact details shall correspond with the Malta Business Register details. 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 calendar 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 calendar 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 321 Medical Devices and In-Vitro Diagnostic Medical Devices Provision on the Maltese Market Regulations, 2020
https://legislation.mt/eli/ln/2020/321/eng/

EU legislations- Medical Devices and In-Vitro Diagnostic Medical Devices
https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

Approvals on file

List of Appendices

N/A