MALTA MEDICINES AUTHORITY

Guidance for Application for Revision or Withdrawal of Medical Device Registration

1. Introduction

A manufacturer or an authorised representative which has its registered place of business in Malta may wish to amend or withdraw medical device/s previously registered with the Malta Medicines Authority under the Medical Device Directives or Regulations.

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

2. Scope

The purpose of this guidance document is to outline the requirements when applying for revision or withdrawal of medical devices. Refer to Medical Devices Regulation (EU) 2017/745, In-Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 and local legislation S.L. 458.59 and L.N. 321.

3. Terms, Definitions and Abbreviations

Abbreviations

DoC: Declaration of Conformity

EMDN: European Medical Device Nomenclature

GMDN: Global Medical Device Nomenclature

IVD: In-Vitro Diagnostic Medical Device

Definitions

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 regard to the latter's obligations under this Regulation. [Regulation (EU) 2017/745 Article 2(32) and Regulation (EU) 2017/746 Article 2(25)]

Authority

Authority in this document refers to the Malta Medicines Authority.

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) and Regulation (EU) 2017/746 Article 2(23)]

Medical Device

A medical device is 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) of the Medical Device Regulation (medical devices, accessories for medical devices, and products listed in Annex XVI) and of those referred to in the first paragraph of this point. [Regulation (EU) 2017/745 Article 2(1)]

4. Documentation required

In order to apply for revision or withdrawal of medical device/s, the applicant must fill in the relevant national form.

4.1 General Details Related to Applying

4.1.1 Application Form Title

The application form related to this guidance document is *MT-MDF03 Application Form for Revision or Withdrawal of Medical Device Registration*, which may be accessed from the Malta Medicines Authority website https://www.medicinesauthority.gov.mt, under the section for medical devices.

4.1.2 Application Format

MT-MDF03 Application Form is in a fillable pdf format. Form should be filled in electronically using the shaded areas. Handwritten forms may not be accepted if writing is considered illegible.
Forms should be signed and submitted as a scanned copy or as a signed pdf file.

4.1.3 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.

4.2 Filling in the Application Form

All sections must be completed. The Application Form is divided as follows:

- Section A: Application Introduction
- Section B: Manufacturer Contact Details
- Section C: Authorised Representative Contact Details
- Section D: Medical Device Details
- Section E: Documentation to be submitted
- Section F: Details of payment
- Data Protection Consent Statement
- Malta Medicines Authority Declaration for Form Submission

4.2.3 Section A: Application Introduction

This section is divided into two sections:

4.2.3.1 Date of Application and applicant details

The date of the application and the details of the applicant should be included in this section. It is the responsibility of the applicant to update the Authority of any changes in the details of the application.

4.2.3.2 Organisation Status

The organisation type making the request, whether the manufacturer or the authorised representative, must be selected.

4.2.4 Section B: Manufacturer Contact Details

The details of the manufacturer should be included in this section. Local organisations should be registered with the Authority and the reference number must be quoted in this section. The Single Registration Number should also be quoted, if available. It is the responsibility of the manufacturer to update the Authority of any changes in these contact details.

4.2.5 Section C: Authorised Representative Contact Details

An Authorised Representative is required when the manufacturer is located outside the Union. The details of the Authorised Representative should be included in this section. Local organisations should be registered with the Authority and the reference number must be quoted in this section. It is the responsibility of the authorised representative to update the Authority of any changes in these contact details.

4.2.6 Section D: Medical Device Details

This section of the form is used to record the device registration details. If more than one device needs to be entered, you are requested to fill in the MT-MDF03 Medical Device Revision or Withdrawal excel sheet and attach it to the application. The sheet can be found on the Medicines Authority website under the medical device section through the following link: https://medicinesauthority.gov.mt/mdforms.

4.2.6.1 Medical Device Registration Type

The applicant shall tick as applicable, to clearly indicate whether the medical device will be withdrawn from the European market or whether an amendment to the registration of the current available product is required.

The device registration number which was given by the Malta Medicines Authority upon the original submission must be provided.

4.2.6.2 Nomenclature

According to Article 26 of Regulation 2017/745 on medical devices and Article 23 of Regulation 2017/746 on in-vitro diagnostic medical devices, the Commission is required to make available a medical device nomenclature to support the functioning of EUDAMED.

Consequently, the applicant shall provide the GMDN or the EMDN code for every device being registered.

4.2.6.3 Additional Device Details

The applicant shall also provide the trade name, generic name, and intended use of the respective device being registered.

4.2.7 Section E: Documentation to be submitted

The documents to be submitted with the application are:

- Declaration/s of Conformity for medical devices registered in this application
- For devices which require a Notified Body: EC Certification
- Instructions For Use – in case of revision
- Labelling of the device (outer pack/label) – in case of revision
- For Authorised Representatives: Notarised copy of the letter of designation
- In case of Revision, the details and justification of the amendment

The Malta Medicines Authority reserves the right to request further documentation as required.

4.2.8 Section F: Details of Payment

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

4.2.8.1 Processing Timeframes

- Standard Service

Upon submission of all the relevant documentation and relevant fees, a standard processing timeframe of thirty (30) working days commences.

- Fast track Service

Upon submission of all the relevant documentation and relevant fees, a fast-track processing timeframe of ten (10) working days commences.

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 stopped upon receipt of responses. If further queries arise or responses are not satisfactory, the applicant is informed, and clock-stop is initiated/stopped accordingly with the cycle repeating itself.

The applicant may withdraw the application at any stage of its processing, by sending an email to *mdforms.medicinesauthority@gov.mt*. It should be noted that in such cases, payments will not be reimbursed or credited.

4.2.8.2 Proof of Payment

The applicant is requested to attach **Proof of Payment**. This document will be verified by the Finance & Corporate Services Unit at the Malta Medicines Authority, confirming receipt of funds.

4.2.9 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).

4.2.10 Malta Medicines Authority Declaration for Form Submission

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

For an application to be considered valid, 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

The Malta Medicines Authority - Medical Devices section

https://medicinesauthority.gov.mt/medicaldevices?l=1

GL-MDF07 Guidance on fees in relation to Medical Devices

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

EU legislations- Medical Devices and In-Vitro Diagnostic Medical Devices

https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

Signatures on File

List of Appendices

N/A