



Guidance for Request for Advice on making available Medical Device / In-Vitro Diagnostic in Malta

1. Introduction

Stakeholders requiring advice on making available Medical Devices or In-Vitro Diagnostics in Malta, are requested to submit application MT-MDF19 *Application Form for Request for Advice on making available Medical Device / In-Vitro Diagnostic in Malta*, providing all the relevant documentation requested in this application form. Only medical devices considered by the Malta Medicines Authority to be in accordance with EU medical device and in-vitro diagnostics legislations shall be placed and made available on the EU market.

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 advice on making available Medical Devices or In-Vitro Diagnostics in Malta.

3. Terms, definitions & abbreviations

Authority

Authority in this document refers to the Malta Medicines Authority.

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)]

In-vitro diagnostic medical device (IVD)

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

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)]

Unique Device Identifier Device Identifier

This is a series of numeric or alphanumeric characters specific to a manufacturer and a device. [Regulation (EU) 2017/745 Article 27(1)(a)(i) & (EU) 2017/746 Article 24 (1)(a)(i)]

4. Documentation required

In order to apply for customs documentation and product compliance evaluation, 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-MDF19 Application Form for Request for Advice on making available Medical Device / In-Vitro Diagnostic in Malta*, may

be accessed from the Malta Medicines Authority website <https://medicinesauthority.gov.mt>, under the section for medical devices.

4.1.2 Application Format

MT-MDF19 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 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 Details
- Section C – Authorised Representative Details
- Section D – Medical Device/In-vitro Diagnostic details
- Section E – Documentation to be submitted
- Data Protection Consent Statement
- Malta Medicines Authority Declaration for Form Submission

4.2.1 Section A: Application Introduction

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.

4.2.2 Section B: Manufacturer Contact Details

The details of the manufacturer should be included in this section. Local organisations should be registered with the Authority. The Malta Medicines Authority organisation registration number and the Single registration number (if available) should be quoted in this section. It is the responsibility of the manufacturer to update the Authority of any changes in these contact details.

4.2.3 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. The Single Registration Number should also be quoted, if available. It is the responsibility of the authorised representative to update the Authority of any changes in these contact details.

If applicable, the Authorised Representative should be included in all correspondence related to this application.

4.2.5 Section D: Medical Device/In-vitro Diagnostic Details

The trade name, the generic name and the intended use of the products included in the application must be provided in this section. The Unique Device Identifier should be filled in for all regulation compliant devices. Legacy devices or devices which have not yet obtained a Unique Device Identifier may omit it, in accordance with applicable timelines indicated in the MDR 2017/745 or IVDR 2017/746.

If more than one device needs to be entered in Section C, you are requested to fill in the MT-MDF19 *Request for Advice on making available Medical Devices in Malta* 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>.

Up to 5 (five) Declarations of Conformity of the same manufacturer can be submitted with each application.

4.2.6 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
- Labelling of the device (outer pack/label)
- Instructions For Use
- Notified Body Certificates (if applicable)
- Proof of Payment

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

4.2.7 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://medicinesauthority.gov.mt>, under the section for medical devices.

4.2.7.1 Processing Timeframes

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

Should the Authority require any further information or clarification, this will be communicated to the applicant and a stop-clock will be initiated. The stop-clock will be 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.

4.2.7.2 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.

4.2.8 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).

4.2.9 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