MALTA
MEDICINES AUTHORITY

Guidance for Application for Customs Documentation and Product Compliance Evaluation

1. Introduction

Stakeholders requiring customs documentation and product compliance evaluation by the Malta Medicines Authority, are requested to submit application MT-MDF22 *Application for Customs Documentation and Product Compliance Evaluation,* 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 customs documentation and product compliance evaluation.

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)]

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.
[Regulation (EU) 2017/745 Article 2(33) & (EU) 2017/746 Article 2(26)]

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)]

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-MDF22 Application for Customs Documentation and Product Compliance Evaluation,* which 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-MDF22 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 – Importer contact details
- Section C – Manufacturer contact details
- Section D – Authorised Representative contact details
- Section E – Medical device/In-vitro diagnostic details
- Section F – 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: Importer Contact Details

The details of the importer 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 importer to update the Authority of any changes in these contact details.

4.2.3 Section C: 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. It is the responsibility of the manufacturer to update the Authority of any changes in these contact details.

4.2.4 Section D: 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.

The Authorised Representative should be included in all correspondence related to this application.

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

The catalogue number, the trade name, the generic name and the intended use of the products included in the application must be provided in this section. The UDI-DI should be filled in for all regulation compliant devices. Legacy devices or devices which have not yet obtained a UDI-DI 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 E, you are requested to fill in the MT-MDF22 Customs Evaluation 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 3 (three) Declarations of Conformity of the same manufacturer can be submitted with each application.

4.2.6 Section F: 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
- Labelling of the device (outer pack/label)
- Photo of the shipment received at customs
- Shipment documentation
- 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.

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.

4.2.7.2 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.

4.3 Validity of Letter of Compliance

The issued Letter of Compliance will have a validity of 1 year from the date of issue.

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