MALTA
MEDICINES
AUTHORITY

Guidance for Application for Medical Device / In-Vitro Diagnostic Evaluation of Risk Classification

1. Introduction

A manufacturer or an authorised representative which has its registered place of business in Malta may request the evaluation of the risk classification of a medical device or an in-vitro diagnostic, by the Malta Medicines Authority. The request may or may not arise from a dispute between the manufacturer and the notified body concerned, on the application of Annex VIII (Classification Rules) of the Medical Device Regulation and the In-Vitro Diagnostic Regulation.

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 requesting evaluation of the risk classification of medical devices/in-vitro diagnostics by the Malta Medicines Authority. 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

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

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)]

Notified Body

A notified body means a conformity assessment body designated in accordance with the Medical Device Regulation and the In-Vitro Diagnostic Regulation. [Regulation (EU) 2017/745 Article 2(42) and Regulation (EU) 2017/746 Article 2(34)]

4. Documentation required

In order to apply for Medical Device / In-Vitro Diagnostic Evaluation of Risk Classification, 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-MDF20 – Application Form for Medical Device / In-Vitro Diagnostic Evaluation of Risk Classification*, 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-MDF20 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 Contact Details
- Section C – Authorised Representative Contact Details
- Section D – Medical Device / In-Vitro Diagnostic 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

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.

The applicant should specify whether the request arises from a dispute between the manufacturer and the Notified Body.

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. 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. 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.

4.2.6 Section D: Medical Device / In-Vitro Diagnostic Details

The medical device details should be recorded in this section, including the trade name, the generic name and the intended use of the device. This section includes the proposed risk classification by the manufacturer and, in case of a dispute between the manufacturer and the notified body, the proposed risk classification by the notified body.

4.2.7 Section E: Documentation to be submitted

- Declaration/s of Conformity for medical devices registered in this application, if available
- Labelling of the device (outer pack/label)
- Instructions For Use
- For Authorised Representatives: Notarised copy of the letter of designation

- Documents with the rationale of the proposed risk classification of the manufacturer. In cases of dispute between the manufacturer and the notified body, the report of the notified body should also be submitted.

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://medicinesauthority.gov.mt, under the section for medical devices. The relevant proof of payment documentation must be attached to the application.

4.2.8.1 Processing Timeframes

Upon submission of all the relevant documentation and relevant fees, a processing timeframe of forty-five (45) working days commences. The fast track option is not applicable to this application.

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