Guidance for Application for Certificates of Free Sale for Medical Devices

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Medical Devices & Pharmaceutical Collaboration Directorate

1. Introduction

A manufacturer or an authorised representative which has its registered place of business in Malta may request the issuance of a Certificate of Free Sale for a medical device. The Certificate of Free Sale issued by the Malta Medicines Authority certifies that the medical device may be legally marketed in the Union.

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 Certificates of Free Sale to 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

Abbreviations:

AIMD: Active Implantable Medical Device

CFS: Certificate of Free Sale

GDPR: General Data Protection Regulation

IVD: In-Vitro Diagnostic Medical Device

IVDD: In-Vitro Diagnostic Directive

IVDR: In-Vitro Diagnostic Regulation

MDD: Medical Device Directive

MDR: Medical Device Regulation

UDI-DI Unique Device Identifier Device Identifier

Definitions:

Active implantable medical device
Active implantable medical device means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure. [Directive 90/385/EEC Article 1(2)c]

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)]

Certificate of Free Sale
A certificate of free sale is a certificate issued by the Member State in which the manufacturer or the authorised representative has its registered place of business, declaring that the manufacturer or the authorised representative, as applicable, has it registered place of business on its territory and that the device in question bearing the CE marking in accordance with the Medical Device Regulation or the In-Vitro Diagnostics Regulation, may be marketed in the Union. It is issued for the purpose of export and upon request by a manufacturer or an authorised representative.
[Regulation (EU) 2017/745 Article 60(1) and Regulation (EU) 2017/746 Article 55(1)]

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)]

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. Specific Guidance

4.1 Applicants applying for a Certificate of Free Sale

The application form for a CFS may be requested by the manufacturer or the authorised representative with a registered place of business in Malta, for the concerned medical device/s.

4.2 Certificates of Free Sale

The Malta Medicines Authority issues three types of certificates for medical devices, depending on the product:

- Medical Device/s
- In-Vitro diagnostic medical device/s
- Active implantable medical device/s

4.3 General Details related to Applying

4.3.1 Application Form Title

The application form related to this guidance document is *MT-MDF01 – Application Form for Certificates of Free Sale (CFS) for Medical Devices*, which may be accessed from the Malta Medicines Authority website https://medicinesauthority.gov.mt, under the section for medical devices.

4.3.2 Application Format

MT-MDF01 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.

4.3.3 Delivery Address

The completed CFS may be sent to the applicant's postal address provided on the application form or collected by hand by the applicant.

4.3.4 Official Languages

The official languages in Malta are Maltese and English. All application forms and supporting documentation for a CFS must be completed in either Maltese or English.

4.4 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 – Information on Certificate of Free Sale
- Section E – Documentation to be submitted
- Section F – Details of Payment
- Data Protection Consent Statement
- Malta Medicines Authority Declaration for Form Submission

4.4.1 Section A: Application Introduction

Section A is divided into two sections:

4.4.1.1 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.

4.4.1.2 Applicant

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

4.4.2 Section B: Manufacturer 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.

4.4.3 Section C: Authorised Representative 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.

4.4.4 Section D: Information on CFS

The information in this section will appear on the CFS.
This section is divided into three parts:

4.4.4.1 Type of Medical Device

This indicates what type of device will be included on the CFS. Only one type may be selected per application:

- Medical Device under the MDR
- In-Vitro Diagnostic Medical Device under the IVDR
- Medical Devices under the MDD
- Active Implantable Medical Device under the AIMD
- In-Vitro Diagnostic medical device under the IVDD

An application form must be completed per Declaration of Conformity.

4.4.4.2 Country for which Certificate of Free Sale is issued

The CFS is issued for the purpose of export. Only one country can be requested per CFS.

4.4.4.3 Devices to be included on the CFS

This section must include a list comprising the product code and the equivalent brief description for each device. This information will be included on the certificate. The description of the product should ideally be kept to one line of text.

The device details may be listed in the *Excel sheet for Application MT-MDF01-Certificate for Free Sale*. The template may be accessed from the Malta Medicines Authority website, under the section for Medical Devices.

4.4.5 Section E: Documentation to be submitted

- Declaration/s of Conformity for medical devices registered in this application
- Notified Body Certificates for relevant device/s
- Instructions For Use
- Labelling of the device (outer pack/label)
- For Authorised Representatives: Notarised copy of the letter of designation
- Copy of the Malta Business Registry Certificate of Company Registration

- If any devices include materials for manufacture which are from animal origin (excluding devices which contain material of animal origin which are externally applied and are not placed in contact of broken skin), kindly attach document which includes details of device, material, animal source and country of origin.

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

4.4.6 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 applicant is to select whether standard or fast track service is required, and the relevant proof of payment document must be attached.

4.4.6.1 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.

4.4.6.2 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.

4.4.7 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).

4.4.8 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.

4.5 CFS Validity

A Certificate of Free Sale is valid for a maximum of **three (3) years** from date of issue or until the applicable transition date listed in Article 120(3) of Regulation (EU) 2017/745 or Article 110(3) Regulation (EU) 2017/746, whichever is the earlier.

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