# Guidance for Application for Certificates of Free Sale for Medical Devices

## 1. Introduction

Certificates of Free Sale for medical devices are issued by a European Competent Authority, upon request by a manufacturer or an authorised representative. The Certificate of Free Sale certifies that the medical device may be legally marketed in Malta and in the European 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

CAB: Conformity Assessment Body

CFS: Certificates of Free Sale

DoC: Declaration of Conformity

e-form: Electronic form

IVD: In-Vitro Diagnostic Medical Device

L.N.: Legal Notice

**Definitions:**

***Active Implantable Medical Device (AIMD)***

Such devices rely on a source of electrical energy or any source of power other than that directly generated by the human body or gravity for its functionality and are 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.

***Authorised Representative***

Where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorised

representative. The authorised representative plays a pivotal role in ensuring the compliance of the devices produced by those manufacturers and in serving as their contact person established in the Union. The authorised representative should be jointly and severally liable with the importer and the manufacturer. The authorised representative is legally liable for defective devices in the event that a manufacturer established outside the Union has not complied with its general obligations.

***Conformity Assessment Body (CAB)***

A body that performs third-party conformity assessment activities including calibration, testing, certification and inspection.

[Regulations (EU) 2017/745 & (EU) 2017/746]

***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.

***In-vitro diagnostic medical device (IVD)***

Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, 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:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

***Manufacturer***

A natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under its own name, regardless of whether these operations are carried out by those persons themselves or on their behalf by a third party.

***Medical Device***

Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,

- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

***Notified Body***

A Conformity Assessment Body (CAB) designated in accordance with Regulations (EU) 2017/745 & (EU) 2017/746.

## 4. Specific Guidance

### 4.1 Applicants for a Certificates of Free Sale (CFS)

The application form for a CFS may be requested by the manufacturer or the authorised representative, for the concerned medical device/s.

### 4.2 CFS

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

- Active implantable medical device (AIMD)
- In-vitro diagnostic medical device (IVD)
- Other medical devices

### 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 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 E-Form

The application is an e-form which must be filled in electronically using the available, grey-shaded areas. Handwritten forms will not be accepted. A signed scanned copy of the completed e-form and supporting documentation must be uploaded.

#### 4.3.3 Delivery Address

The completed CFS will be sent to the applicant's postal address provided on the application form.

#### 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 CFS
- Section E – Documents attached to the Application
- 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 application for the CFS will be completed automatically. The individual completing the application shall provide their name, surname, email address and contact number.

##### 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 here. 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

If this section is completed, the authorised representative's details will appear on the CFS. 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 in the CFS. Only one type may be selected per application:

- Active implantable medical device
- In-vitro diagnostic medical device
- Other medical devices

An application form must be completed per Declaration of Conformity (DoC).

**4.4.4.2 Devices to be included on the CFS**

This section must include a list comprising of 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.

**4.4.4.3 UDI-DI of the devices to be included on the CFS**

If applicable, this section must include the UDI-DI of the devices which are to be included on the certificate.

### 4.4.5 Section E: Documents attached to the Application

A) *Proof of Manufacture* provided in the form of a notarised document:

The proof of manufacture is required when an organisation makes the request for a CFS. An original notarised document must be sent to the Malta Medicines Authority by post and a scanned copy attached to the e-form. A notarised document is a statement made by the manufacturer on the organisation's letterhead paper, signed by a designated representative, stamped and signed by a public notary based within Malta or one within the country of origin. If the notarised document is being submitted by the European authorised representative, it will also need to be signed by a designated representative of the manufacturer. The following information is to be included:

i. Details of the organisations – name and address of the manufacturer and the authorised representative (if applicable)
ii. Details of devices concerned – listed by product code and description

The organisation should notify the Malta Medicines Authority of any changes to this listing, including the addition/withdrawal of any device/s.

A) DoC may be used instead of a Proof of Manufacture document. The DoC would not require notarisation.

B) *Notified Body Certificates* for relevant device/s

A scanned copy of the current notified body certificate for the relevant device/s must accompany the application. Updated versions of the notified body certificates or new notified body certificates for new devices should be forwarded to the Malta Medicines Authority. This document must list the sites of manufacture. The EC Design Examination Certificate for Class III devices must also be attached, if applicable. These certificates must have at least six months' validity remaining after submission.

The device registration number, issued by the Malta Medicines Authority, for the product/s which are to be listed on the CFS is required, for the following devices:

- Class 1 devices
- Custom-made devices
- Systems and procedure packs under Article 12 of the MDD and Article 22 of the MDR

### 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 Service

Upon submission of all the relevant documentation, a standard processing timeframe of 30 calendar days commences.

- Standard Service

Standard processing timeframe from receipt of the application form at Malta Medicines Authority.

- Fast track Service

Fast track processing of 10 calendar days from receipt of the application form at Malta Medicines Authority.

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 restarted upon receipt of responses. If further queries arise or responses are not satisfactory, the applicant is informed, and clock stops/starts accordingly with the cycle repeating itself.

#### 4.4.6.2 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 Documents Required

The documents to be submitted with this application form are:

- Proof of manufacture in the form of a notarised document (original) or Declaration of Conformity (softcopy)
- Notified Body Certificate for relevant device/s (softcopy)
- Malta Business Registry Certificate of Company Registration (softcopy)

- Mock-Ups of the label, packaging and instructions of use (softcopy)
- Notarised copy of the letter of designation between the manufacturer and the European authorised representative (softcopy, if applicable)
- Proof of payment (softcopy)

**Any additional documents relevant to the function of the organisation/medical device must be made available to the Malta Medicines Authority, upon request.**

### 4.6 CFS Validity

The CFS is valid for a period of three years from the date of issue. Following this period, a new application must be submitted. Where a CFS has been issued and the registration of a medical device is not continued for whatever reason, it is the responsibility of the organisation, to which the certificate is issued, to withdraw from circulation the certificate which lists such devices.

**For an application to be considered, 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

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

Legal Notice 321 Medical Devices and In-Vitro Diagnostic Medical Devices Provision on the Maltese Market Regulations, 2020
https://legislation.mt/eli/ln/2020/321/eng

EU legislations- Medical Devices and In-Vitro Diagnostic Medical Devices
https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

*Approvals on file*

List of Appendices

N/A