Guidance for Application for Medical Devices Registration to place Medical Devices on the EU Market

1. Introduction

The application form for the registration of medical devices is being presented by the Malta Medicines Authority. This requires a collaborative approach from all economic operators in this field and aims to expand the impact, scale and coordination of surveillance and activity in the transparency and accountability field, as well as to explore applications of this work in new areas.

2. Scope

The purpose of this guidance document is to provide comprehensive instructions to the applicant when registering the medical devices which a particular economic operator places on the EU market.

3. Terms, Definitions and Abbreviations

Abbreviations

CAB: Conformity Assessment Body

DoC: Declaration of Conformity

e-form: Electronic Form

EU: European Union

GMDN: Global Medical Device Nomenclature

IVD: In-Vitro Diagnostic Medical Device

Definitions

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]

European Database on Medical Devices (EUDAMED)

EUDAMED is the European databank for medical devices. It is a secure, web-based portal which enables the exchange of information between National Competent Authorities and the European Commission.

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.

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

4. Specific Guidance

4.1 Applicants applying through the Medical Devices Registration Form

The application form for the registration of medical devices may be requested solely by manufacturers or authorised representatives in relation to the registration of medical devices placed on the EU market. The applicants requesting the application may be first time users or registered users who aspire to make further amendments to the details of the medical devices' specifications originally submitted in the registration application form at the National Competent Authority. Alternatively, the applicant requesting the application may aspire to withdraw or amend the medical device/s which are available on the EU market.

4.2 General Details related to Applying

4.2.1 Application Form Title

The application form related to this guidance document is *MT-MDF03 - Application Form for Medical Device Registration to place Medical Devices on the EU Market*, which may be accessed from the Malta Medicines Authority website https://medicinesauthority.gov.mt/ , under the section for medical devices.

4.2.2 E-Form

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

4.2.3 Delivery Address

Once the registration form has been successfully received, an acknowledgment will be sent to the applicant's electronic address provided on the application form.
Once registration is complete, the assigned *EUDAMED 2 Number* for each medical device product registered, will be sent to the applicant.

4.2.4 Official Languages

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

4.3 Filling in the Registration Form

All sections must be completed if the applicant is an authorised representative.
If the applicant is a manufacturer, *Section C – Authorised Representative Contact Details* shall not be filled in.

The Registration Form is divided as follows:

- Section A: Application Introduction
- Section B: Manufacturer Contact Details
- Section C: Authorised Representative Contact Details
- Section D: Medical Device Details
- Section E: Details of Payment
- Data Protection Consent Statement
- Malta Medicines Authority Declaration for Form Submission

4.3.1 Section A: Application Introduction

This section is divided into two sections:

4.3.1.1 Date of Application and applicant details

The date of application will be completed automatically. The individual completing the application shall provide their name, surname, email address and contact number.

4.3.1.2 Organisation Status

The organisational status of the entity, which will be registering the medical devices placed on the EU market with the National Competent Authority shall be indicated. *Section 3 – Definitions* of this guidance document may be used as a reference.

4.3.2 Section B: Manufacturer Contact Details

This section must be filled in by manufacturers established within the EU.

The manufacturer contact details shall correspond with the details on the Declaration of Conformity (DoC) of the medical device being registered.

It is advisable to quote the reference number provided by the Malta Medicines Authority, if the organisation has previously been registered.

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

4.3.3 Section C: Authorised Representative Contact Details

This section must be filled by any natural or legal person established within the EU who has received and accepted a written mandate from the manufacturer, located outside the EU, to act on the manufacturer's behalf in relation to specified tasks with regards to the latter's obligations under Regulation (EU) 2017/745 and (EU) 2017/746.

It is advisable to quote the reference number provided by the Malta Medicines Authority, if the authorised representative has previously been registered.

It is the responsibility of the authorised representative to update the Authority of any changes in these contact details.

4.3.4 Section D: Medical Device Details

This section of the form is used to record the device registration details which are available on the EU market. One application shall be completed per DoC, Section D must be completed for each individual device registration.

4.3.4.1 Medical Device Registration Type

The applicant shall tick as applicable to clearly indicate the type of application that will be submitted to the National Competent Authority. To make an amendment to a previously registered device please provide the device registration number in the grey shaded box, which was given by the Malta Medicines Authority upon original submission.

In the case of an amendment registration application, the applicant shall tick if the medical device will be amended from the current available product or withdrawn from the EU market.

4.3.4.2 Medical Devices (other than IVD)

This section is divided into two sections:

- **Classification of Medical Device, other than IVD**

In this section the applicant shall identify under which category the device will be registered. Please tick the relevant box.

	Regulation (EU) 2017/745
Class I devices	Article 52 (7)
Custom-made devices	Article 52 (8)
System or procedure packs	Article 22
Other medical devices	This category is reserved for sterilisation companies who may in addition to the above classes of devices, sterilise other CE marked devices for placing on the market under their own name

- **Additional information for Medical Device, other than IVD**

Class I, are further divided into sterile devices and devices with a measuring function.

The term ‘sterile device’ refers to devices that are placed on the market in a sterile condition, whereas ‘devices with a measuring function’ have a metrological function.

4.3.4.3 IVD Details

This section is further divided into two sections:

- **Classification of IVD**

The classification of the in-vitro diagnostic medical devices shall be done in a concise and accurate manner.

Devices of List A comprise of:

- Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: ABO system, rhesus (C, c, D, E, e) and anti-Kell
- Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D
- Variant Creutzfeldt-Jakob disease (vCJD) assays for blood screening, diagnosis and confirmation

Devices of List B comprise of:

- Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: anti-Duffy and anti-Kidd
- Reagents and reagent products, including related calibrators and control materials, for determining irregular anti-erythrocytic antibodies
- Reagents and reagent products, including related calibrators and control materials, for the detection and quantification in human samples of the following congenital infections: rubella and toxoplasmosis
- Reagents and reagent products, including related calibrators and control materials, for diagnosing the following hereditary disease: phenylketonuria
- Reagents and reagent products, including related calibrators and control materials, for determining the following human infections: cytomegalovirus and chlamydia
- Reagents and reagent products, including related calibrators and control materials, for determining the following HLA tissue groups: DR, A and B

Devices for self-testing (other than List B):

A device for self-testing means any device intended by the manufacturer to be able to be used by lay persons in a home environment. Simultaneously, devices for self-testing must be designed and manufactured in such a way that they perform appropriately for their intended purpose, taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in users' technique and environment.

All other IVDs

Any other IVDs which do not fall in the above-mentioned lists.

- **Notified body number (if applicable)**

In this case, the applicant shall quote the notified body number. A copy of the relevant CE certification must be provided.

4.3.4.4 Nomenclature

According to Article 26 of Regulation 2017/745 on medical devices and Article 23 of Regulation 2017/746 on in-vitro diagnostic medical devices, the Commission is required to make available a medical device nomenclature to support the functioning of EUDAMED.

Consequently, the applicant shall provide the GMDN code for every device being registered.

4.3.4.5 Additional Device Details

The applicant shall also provide the trade name, generic name, and intended use of the respective device being registered.

4.3.5 Section E: 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 relevant proof of payment documentation must be attached.

4.3.5.1 Service

Upon submission of all 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.

4.3.5.2 Proof of Payment

This document will be verified by the Finance & Corporate Services Unit at the Malta Medicines Authority, confirming receipt of funds.

4.3.6 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).

4.3.7 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.

4.4 Documents Required

The documents to be submitted with this Application Form are:

- Declaration of Conformity (DoC) (softcopy)
- Notarised copy of the letter of designation between the manufacturer and the European authorised representative (softcopy, if applicable)
- Copy of CE certification if a notified body is involved (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.

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/pdf

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