Guidance for Application for Notification of Medical Devices Made Available on the Local Market

1. Introduction

The application form for medical device notification is being presented by the Malta Medicines Authority (MMA) to increase transparency and traceability of medical devices being put on the local market. This will allow the National Competent Authority to identify and track medical devices across the Maltese islands if the need arises.

Any further clarification on this guidance document may be obtained from MMA, by sending an email to *mdforms.medicinesauthority@gov.mt*.

2. Scope

The purpose of this guidance document is to provide comprehensive instructions to the user on how to notify the placement of a medical device on the local market with the National Competent Authority. This guidance is intended to offer a robust approach towards the proficiency and control of how the user must accurately complete and submit the application form.

3. Terms, Definitions and Abbreviations

Authorised Representative

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 the Regulations.
[Regulation (EU) 2017/745 & (EU) 2017/746]

Basic UDI-DI

The primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.
[Regulation (EU) 2017/745 & (EU) 2017/746]

Distributor

Any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.
[Regulation (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.

[Regulation (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, 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]

Manufacturer

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 & (EU) 2017/746]

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) and of those referred to in the first paragraph of this point.

[Regulation (EU) 2017/745]

Unique Device Identification (UDI)

A series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.

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

UDI-DI

A unique numeric or alphanumeric code specific to a model of device and that is also used as the 'access key' to information stored in a UDI database.

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

Variant

A variant means a variation of a device that does not change the intended purpose. Variations include, but not limited to, size, colour and version.

Example 1: Wrist support with splint, wrist support without splint, hand and wrist support without splint of the same brand are not considered variants, but separate devices and therefore requiring individual fee.

Example 2: Syringes of same brand, different volume (mL) sizes, require one notification fee.

Example 3: Catheters of same brand, different gauges, require one notification fee.

Abbreviations:

DoC:	Declaration of Conformity
EUDAMED:	European Database on Medical Devices
GDPR:	General Data Protection Regulation
IVD:	In vitro diagnostic medical device
MMA:	Malta Medicines Authority
UDI:	Unique Device Identification
UDI-DI:	Unique Device Identification - Device Identifier

4. Specific Guidance

4.1 Applicants applying through the Medical Device Notification Form

The application form for notification of a medical device made available on the local market, may be submitted by an importer or a distributor. The applicants submitting the application must be registered users. The applicant may create a new notification or make amendments in details of a previously notified medical device.

4.2 General Details related to Applying

Application Form Title

The application form related to this guidance document is *MT-MDF05 - Application Form for Notification of Medical Devices Made Available on the Local Market*, which may be accessed from the MMA website https://medicinesauthority.gov.mt/medicaldevices.

Application Format

The application is in a fillable pdf format 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 application and supporting documentation must be submitted.

Acknowledgement

Once the application form has been successfully received and reviewed, an acknowledgment will be sent to the applicant's electronic address.

Official Languages

The official languages in Malta are Maltese and English. The application form and all supporting documentation must be completed in either Maltese or English.

4.3 Filling in the Application Form

All sections must be completed.

The Registration Form is divided as follows:

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

<u>Section A: Application Introduction</u>

This section is divided into two sections:

Date of Application and applicant details

The individual completing the application shall provide the following information: Date of the application, applicant's name, surname, email address and contact number.

Applicant Organisation Details
The applicant organisation name and the organisation registration number must be inputted in the fields provided. The organisation registration number is given to organisations that have already registered with the MMA. For further information on organisation registration kindly refer to guidance document *GL-MDF02 'Guidance for Application for Organisation Registration in relation to Medical Devices'* and application *MT-MDF02 'Application Form for Organisation Registration in relation to Medical Devices'* which may be accessed from the MMA website https://medicinesauthority.gov.mt/medicaldevices.

Section B: Manufacturer Details

The manufacturer contact details shall correspond with the details on the Declaration of Conformity (DoC) of the medical device being notified. It is the responsibility of the manufacturer to update the MMA of any changes in these contact details.

Section C: Authorised Representative Contact Details

This section must be completed in the event that the manufacturer is not located in an EU Member State. In such a case, both contact details of the authorised representative, and the manufacturer they represent need to be filled in. It is the responsibility of the authorised representative to update the MMA of any changes in these contact details.

Section D: Medical Device Details

Notification Type
The applicant shall tick whether this is a first-time notification of a medical device or a previously notified device requiring an amendment.
If the application aims to amend a previously notified medical device, the applicant must tick, as appropriate, either withdrawal or revision to the current details.

Device Notification Sheet
The applicant must list all devices, excluding variants. Refer to definition of variant in this Guidance.

The device notification sheet has the following headings:
Reference Number, Product Brand Name, Generic Name, Catalogue Number, Device Type, Class and, where applicable, Basic UDI-DI/UDI-DI.

Reference Number:
The number of the medical device if the device has been registered previously.

Product Brand Name:
Mandatory, the product brand name of the medical device as written on the DoC.

Generic Name:
Mandatory, the generic name of the medical device as written on the DoC.

Catalogue Number:
Mandatory, the catalogue number of the medical device as written on the DoC.

Device Type:
Mandatory, the type of the medical device as written on the DoC.

Class:
Mandatory, the Class of the medical device as written on the DoC.

Basic UDI-DI:
Where applicable, the Basic UDI-DI of the medical device as written on the DoC.

UDI-DI:
Where applicable, the UDI-DI of the medical device as written on the DoC.

Section E: Details of Payment
Reference should be made to the *GL-MDF07 Guidance on fees in relation to Medical Devices* available on the MMA website https://medicinesauthority.gov.mt/medicaldevices. The relevant proof of payment document must be attached.

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 MMA.

- Fast Track Service

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

Should the MMA require any further information or clarification, this will be communicated to the applicant. A stop-clock will be initiated, and the clock will be 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.

Proof of Payment
This document will be verified by the Finance & Corporate Services Unit at the MMA, confirming receipt of funds.

Data Protection Consent Statement
Applicant shall confirm consent, by ticking the box in this section, to the processing of personal data by the MMA and understands that this data shall be processed in accordance with the General Data Protection Regulation (GDPR).

Malta Medicines Authority Declaration for Form Submission
Applicant shall sign the MMA declaration that all the information submitted within this request form is correct and complete.

4.4 Documents Required

The documents to be submitted with this application form are:

- 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 MMA, 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

Subsidiary Legislation 458.61 - *Testing of COVID-19 Regulations*
https://legislation.mt/eli/sl/458.61/eng

EU legislations:
https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

Signatures on file

List of Appendices

N/A