Guidance for Application to be submitted when applying for Designation as a Notified Body under the Medical Devices Regulation (EU) 2017/745 (MDR) / InVitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR)

1. Introduction

Malta Medicines Authority is the National Competent Authority designating conformity assessment bodies as Notified Bodies with respect to medical devices in accordance with the following Regulations: Medical Devices Regulation (EU) 2017/745 and In-Vitro Diagnostic Medical Devices Regulations (EU) 2017/746.

2. Scope

The purpose of this guidance document is to provide comprehensive instructions to the user on how to apply for designation as a Notified Body with the National Competent Authority.

3. Terms, Definitions and Abbreviations

Abbreviations

CAB	Conformity assessment body
NB	Notified Body
IVDR	Regulation (EU) 2017/746 of the European Parliament of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices and Repealing Directive 98/79/EC and Commission Decision 2010/227/EU
MDCG	Medical Devices Coordination Group
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Repealing Council Directives 90/385/EEC and 93/42/EEC
e-form:	Electronic form

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.

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]

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 (NB)

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 for Designation as a Notified Body under the Medical Devices Regulations (EU) 2017/745 (MDR)/In-Vitro Diagnostic Medical Devices Regulations (EU) 2017/746 (IVDR)

This application form is requested by a CAB seeking designation as a NB for medical devices or a NB wishing to renew designation or make extensions to their scope.

4.2 General Details related to Applying

4.2.1 Application Form Title

The application form related to this guidance document is *MT-MDF06 - Application Form to be submitted when applying for designation as a Notified Body under the Medical Devices Regulation (EU) 2017/745 (MDR)/In-Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR)* which may be accessed from the Malta Medicines Authority websitehttps://medicinesauthority.gov.mt/ , under the section for medical devices.

4.2.2 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.

4.2.3 Acknowledgement

Once the registration form has been received an acknowledgment email will be sent.
A communication letter will be sent to the applicant verifying that all documents required for the commencement of the designation review process have been received.

4.2.4 Official Languages

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

4.3 Filling in the Application Form

All sections must be completed. The application form is divided as follows:

- Section A: Application Introduction
- Section B: Applying Conformity Assessment Body Details
- Section C: Details of Payment
- Data Protection Consent Statement
- Malta Medicines Authority Declaration for Form Submission

4.3.1 Section A: Application Introduction

Section A is divided into two sections:

4.3.1.1 Date of application

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

4.3.1.2 Type of application

The applicant must indicate whether the application is an initial application, renewal or an application for extension of scope by ticking the appropriate box. Should it be a renewal or application for an extension of scope, the applicant must quote the organisation registration number in the grey-shaded area provided.

4.3.2 Section B: Applying Conformity Assessment Body Details

4.3.2.1 Applying CAB Contact Details

The details of the CAB should be included here. It is the responsibility of the applicant to update the Authority of any changes in these contact details.

4.3.2.2 Application for Designation Under

The applicant must choose whether designation is under the Medical Devices Regulations (EU) 2017/745 (MDR) or the In-Vitro Diagnostic Medical Devices Regulations (EU) 2017/746 (IVDR) and tick appropriately.

4.3.2.3 Medical Device Coordination Group (MDCG) Forms

The latest relevant Medical Device Coordination Group (MDCG) forms must be completed and attached to the application form. These include:

- MDCG 2021-15: Application form to be submitted by a conformity assessment body when applying for designation as notified body under Regulation (EU) 2017/745 on medical devices (MDR)

- MDCG 2021-16: Application form to be submitted by a conformity assessment body when applying for designation as notified body under Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)

- MDCG 2021-17: Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/745)

- MDCG 2021-18: Applied-for scope of designation and notification of Conformity Assessment Body Regulation (EU) 2017/746 (IVDR)

4.3.3 Section C – 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 websitehttps://medicinesauthority.gov.mt/ , under the section for medical devices. The relevant proof of payment document must be attached.

4.3.3.1 Service

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

Should the Authority 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.

4.3.3.2 Proof of Payment

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

4.3.4 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).

4.3.5 Malta Medicines Authority Declaration for Form Submission

Applicant shall sign the Malta Medicines Authority declaration that all the information submitted with this request form is correct and complete.

4.4 Documents required

The documents to be submitted with this Application Form are:

- Completed MDCG forms (softcopy)
- Accompanying electronic documents relevant to the MDCG forms submitted (softcopy)
- Proof of payment (softcopy)

Any additional documents relevant to the function of the organisation 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.

6. 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

Form MDCG 2021-15 for designation under the MDR - *Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices Regulation (MDR)*

Form MDCG 2021-16 for designation under the IVDR - *Application form to be submitted by a conformity assessment body when applying for designation as notified body under the in vitro diagnostic devices Regulation (IVDR)*

Form MDCG 2021-17 for designation under the MDR – *Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/745*

Form MDCG 2021-18 for designation under the MDR – *Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/746 (IVDR)*

Approvals on file

List of Appendices

N/*A*