# Guidance for Application to be submitted when applying for Designation as a Notified Body / Extension for Scope under the Regulations (EU) 2017/745 or 2017/746

## 1. Introduction

Malta Medicines Authority is the Authority for designation of 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, and the Authority responsible for their oversight.

## 2. Scope

The purpose of this guidance document is to provide comprehensive instructions to the applicant on application form MT-MDF-06.

## 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 |

### Definitions

***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]

***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 / extension for scope under the Regulations (EU) 2017/745 or 2017/746

This application form is requested by a Conformity Assessment Body (CAB) seeking designation as a Notified Body (NB) for medical devices or a NB wishing to apply for extension 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 when applying for Designation as a Notified Body / Extension for Scope under the Regulations (EU) 2017/745 or 2017/746* which may be accessed from the Malta Medicines Authority website, section for medical devices: https://medicinesauthority.gov.mt/medicaldevices.

#### 4.2.2 Form
The application is a 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 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 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: Applying for Designation as a Notified Body under Regulations (EU) 2017/745 MDR / (EU) 2017/746 IVDR
- Section D: Applying for Extension of Scope of Designation
- Section E: EU MDCG Forms to complete on Application for Designation or Extension to Scope
- Section F: 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 (Section A.1)

The applicant completing the application shall provide date of application submission, applicant name and surname, email address and contact number.

##### 4.3.1.2 Type of application (Section A.2)

The applicant must indicate whether the application is an initial application or an application for extension of scope by ticking the appropriate box. Should it be an application for an extension of scope, the applicant must quote the Initial Application Reference 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 (Section B.1)

This section should be completed by including the details of the CAB. It is the responsibility of the applicant to update the Authority of any changes in these contact details.

#### 4.3.3 Section C: Applying for Designation as a Notified Body under Regulations (EU) 2017/745 MDR / (EU) 2017/746 IVDR

#### 4.3.3.1 Applying for Designation under the MDR / IVDR (Section C.1)

The applicant must indicate whether application for designation is under the Medical Devices Regulations (EU) 2017/745 (MDR) or the In-Vitro Diagnostic Medical Devices Regulations (EU) 2017/746 (IVDR), ticking appropriately.

#### 4.3.3.2 CAB already designated under MDR or IVDR (Section C.2)

If CAB is already designated, NB to quote Notified Body's Identification Number.

### 4.3.4 Section D: Applying for Extension of Scope of Designation

#### 4.3.4.1 Applying for Extension of Scope under the MDR / IVDR (Section D.1)

The applicant must indicate whether application for designation is under the Medical Devices Regulations (EU) 2017/745 (MDR) or the In-Vitro Diagnostic Medical Devices Regulations (EU) 2017/746 (IVDR), ticking appropriately.

#### 4.3.4.2 Quoting Notified Body Number (Section D.2)

NB to quote Notified Body's Identification Number.

### 4.3.5 Section E: EU MDCG Forms to complete on Application for Designation or Extension to Scope

#### 4.3.5.1 EU Medical Devices Coordination Group (MDCG Forms (Section E.1)

The latest relevant Medical Device Coordination Group (MDCG) forms must be completed and attached to the application form, accessible via the following link: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec14 These include:

- MDCG 2021-15 rev.1: Application form to be submitted by a conformity assessment body when applying for designation as notified body under the Medical Devices (MDR)

- MDCG 2021-16 rev.1: 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)

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

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

### 4.3.6 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, section for medical devices: https://medicinesauthority.gov.mt/medicaldevices. The relevant proof of payment document must be attached.

#### 4.3.6.1 Service

Upon submission of all the relevant documentation, the processing commences.

Should the Authority require any further information or clarification, this will be communicated to the applicant.

#### 4.3.6.2 Proof of Payment

This document will be verified by the Finance & Corporate Services Unit at the Malta Medicines Authority.

#### 4.3.7 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).

#### 4.3.8 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.**

## 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

EU legislation and guidance documents
Guidance - MDCG endorsed documents and other guidance - European Commission

EU Form: MDCG 2021-15 rev.1 – *Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices Regulation (MDR)*

EU Form: MDCG 2021-16 rev.1 – *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)*

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

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

MT Form: MT-MDF06 – *Application when applying for Designation as a Notified Body / Extension for Scope under the Regulations (EU) 2017/745 or 2017/746*

## 6.

*Signatures on file*

List of Appendices

N/A