



MALTA

**MEDICINES
AUTHORITY**

For office use only: Appl. For NB Designation received on:
Project (Application) No. of Designating Authority:
Organisation Reference No.:

MT-MDF06
**Application Form¹ 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)**

The application is valid when submitted with the relevant documents and fees, where applicable.

Refer to the *Guidance for Application when applying for Designation as Notified Body under the Medical Devices Regulation (EU) 2017/745 (MDR) / In-Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR)* and *Guidance on fees in relation to Medical Devices.*

Guidance and Application Form are available on the Malta Medicines Authority website www.medicinesauthority.gov.mt.

¹ This form should be used for making initial applications, renewal applications and applications for extensions to scope.

June 2023

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www.medicinesauthority.gov.mt

SECTION A: APPLICATION INTRODUCTION

<p><i>A.1 Date of Application (dd/mm/yyyy):</i></p> <p><i>Applicant Name & Surname:</i></p> <p><i>Applicant Email Address:</i></p> <p><i>Applicant Contact Number:</i></p>
<p><i>A.2 Type of Application (tick as applicable):</i></p> <p><input type="checkbox"/> Initial Application</p> <p><input type="checkbox"/> Renewal Application ²</p> <p><input type="checkbox"/> Applications for Extensions to Scope ²</p> <p>² Quote Organisation Registration No.:</p>

SECTION B: APPLYING CONFORMITY ASSESSMENT BODY DETAILS

<i>B.1 Applying Conformity Assessment Body (CAB) Contact Details</i>	
CAB Name:	Telephone Number:
Address:	Contact Name:
	Job Title:
	Email address:
Company Registration Number:	
Notified Body's Identification Number (where applicable):	
<i>B.2 Application for Designation under: (tick as applicable)</i>	
<input type="checkbox"/> Medical Devices Regulation (EU) 2017/745 (MDR)	

In-Vitro Diagnostic Devices Regulation (EU) 2017/746 (IVDR)

B.3 Medical Devices Coordination Group (MDCG) Forms

Complete and attach the latest, relevant Medical Devices Coordination Group (MDCG) Forms

SECTION C: DETAILS OF PAYMENT

Proof of Payment attached

Data Protection Consent Statement

The applicant hereby consents 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), Regulation 2016/679/EU of the European Parliament and of the Council of 27 April 2016, repealing Directive 95/46 EC the Data Protection Act (Chapter 586 of the Laws of Malta) and the Malta Medicines Authority Data Protection Policy (P-MA05). The applicant also understands that the Malta Medicines Authority shall process this personal data in line with the purposes they are initially collected for. Exceptions to the latter include when the data subject consents to the new purpose, when there is a legal provision requiring or allowing the new processing or when the new purpose is deemed compatible with the purposes the personal data were initially collected for.

Malta Medicines Authority Declaration for Form Submission

I, the applicant, declare that all information given in the application form is true, complete and correct. I also bind myself to inform immediately any change to details in the application form and annexes, where relevant, to the Malta Medicines Authority.

Company Name (if applicable):

Name & Surname:

Position:

Signature:

Date: