

*For office use only:* Application No.:

**MT-MDF06**

**Application when applying for**

**Designation as a Notified Body / Extension for Scope**

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

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

Refer to GL-MDF06-05 *Guidance on Application when applying for Designation as a Notified Body / Extension for Scope under the Regulations (EU) 2017/745 or 2017/746* and *Guidance on fees in relation to Medical Devices*.

National guidance document/s are available on the Malta Medicines Authority website: [www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt)

July 2025

**Section A: Application Introduction**

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| *A.1 Date of Application* (dd/mm/yyyy): Click or tap to enter a date.  *Applicant Name & Surname:* Click or tap here to enter text.  *Applicant Email Address:* Click or tap here to enter text.  *Applicant Contact Number:* Click or tap here to enter text. |
| *A.2 Type of Application* (tick as applicable):  Initial Application  Application for Extension to Scope:  Quote Initial Application Reference No.: Click or tap here to enter text. |

**Section B: CONFORMITY ASSESSMENT BODY DETAILS**

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| *B.1 Conformity Assessment Body (CAB) Contact Details* | |
| CAB Name: Click or tap here to enter text. | Telephone Number: Click or tap here to enter text. |
| Address:  Click or tap here to enter text. | Contact Name: Click or tap here to enter text. |
| Job Title: Click or tap here to enter text. |
| Email address: Click or tap here to enter text. |
| Company Registration Number: Click or tap here to enter text. | |

**Applicant to complete Section C or Section D, as applicable.**

**Section C: APPLYING for designation AS A Notified BODY UNDER REGULATIONS (EU) 2017/745 MDR / (eu) 2017/746 IVDR**

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| *C.1 Application for Designation under:* (tick as applicable) |
| Medical Devices Regulation (EU) 2017/745 (MDR)  *In Vitro* Diagnostic Devices Regulation (EU) 2017/746 (IVDR) |
| *C.2 If CAB already designated under MDR or IVDR, Quote Notified Body Number:*  Notified Body's Identification Number: Click or tap here to enter text. |

**Section d: APPLYING for extension of scope of designation**

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| *D.1 Application for Extension of the Scope of Designation under:* (tick as applicable) |
| Medical Devices Regulation (EU) 2017/745 (MDR) |
| *In Vitro* Diagnostic Devices Regulation (EU) 2017/746 (IVDR) |
| *D.2 Quote Notified Body Number:*  Notified Body's Identification Number: Click or tap here to enter text. |

**Section e: eu MDCG FORMS TO COMPLETE ON APPLICATION FOR DESIGNATION OR EXTENSION TO SCOPE**

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| *E.1 EU Medical Devices Coordination Group (MDCG) Forms* |
| Complete and attach the latest, relevant EU Medical Devices Coordination Group (MDCG) Forms  [**https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance\_en#sec14**](https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec14) |

**Section F: 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.*

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**Malta Medicines Authority Declaration for Form Submission**

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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.

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| Company Name (if applicable): | Click or tap here to enter text. |
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| Name & Surname: | Click or tap here to enter text. |
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|  |  |
| Position: | Click or tap here to enter text. |
| Signature: |  |
|  |  |
| Date: | Click or tap to enter a date. |
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