

*For office use only:* Medical Device Registration Form received on: \_\_ / \_\_ / \_\_\_\_

Medical Device Registration Form Reference No.

**MT-MDF23**

**Application Form for Device Registration** **to place devices on the EU Market –**

**Manufacturers / Authorised Representatives**

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

Refer to GL-MDF07 *Guidance on fees in relation to Medical Devices*.

Guidelines are available on the Malta Medicines Authority Website [www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt)/medicaldevices.

Application form and supporting documents are to be submitted to mdforms.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 Applicant Organisation Status* (tick as applicable):  Manufacturer\* (fill in Section B)  Authorised Representative\* (fill in Sections B & C)  \**with a registered place of business in Malta* |

**Section B: Manufacturer: Contact Details**

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| Organisation 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. |
| Malta Medicines Authority Organisation Registration Number: Click or tap here to enter text. | |
| Single Registration Number (SRN): Click or tap here to enter text. | |

**Section C: Authorised representative Contact Details**

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| --- | --- |
| Organisation 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. |
| Malta Medicines Authority Organisation Registration Number: Click or tap here to enter text. | |
| Single Registration Number (SRN): Click or tap here to enter text. | |

**Section D: MEDICAL DEVICE details**

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| **Medical Device Registration Type (tick as applicable):**  Initial Registration  **Legislation (tick as applicable):**  Regulation (EU) 2017/745  Regulation (EU) 2017/746  **Nomenclature:**  Device GMDN Code: Click or tap here to enter text.  Device EMDN Code: Click or tap here to enter text. |

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| **Additional Device Details:**  Generic Name: Click or tap here to enter text.  Intended Use: Click or tap here to enter text. |

*You are requested to fill in the MT-MDF23 Device Registration excel sheet and*

*attach it to the application.*



**SECTION e: DOCUMENTATION TO BE SUBMITTED**

Declaration/s of Conformity for medical devices registered in this application

For devices which require a Notified Body: EC Certification

Instructions For Use

Labelling of the device

For Authorised Representatives: Copy of letter of designation issued by the manufacturer

For non-EU Manufacturers: Declaration of devices being registered through EU Authorised Representative based in Malta

MT-MDF23 Device Registration Sheet

***The Malta Medicines Authority reserves the right to request further documentation as required.***

**Section F: details of payment**

Standard

Fast Track

Proof of Payment attached

**Data Protection Consent Statement**

*The applicant hereby consents to the processing of their 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. |
|  |  |
|  |  |
| Position: | Click or tap here to enter text. |
| Signature: |  |
|  |  |
| Date: | Click or tap to enter a date. |
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