

*For office use only:* Application Reference No.:

**MT-MDF01**

**Application Form for Certificates of Free Sale (CFS) for Medical Devices**

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

Refer to GL-MDF01 *Guidance for Application for Certificates of Free Sale for Medical Devices* and GL-MDF07 *Guidance on fees in relation to Medical Devices* on the Malta Medicines Authority website <https://medicinesauthority.gov.mt/medicaldevices>.

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* (tick as applicable):  Manufacturer (fill in Section B)  Authorised Representative (fill in Sections B and C) |

**Section B: Manufacturer 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: Click or tap here to enter text. | |

**Section C: Authorised Representative 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: Click or tap here to enter text. | |

**Section D: information on Certificate of Free Sale**

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| *D.1 Type of Medical Device* (tick as applicable):  Medical Device under the MDR  In-Vitro Diagnostic Medical Device under the IVDR  Medical Devices under the MDD  Active Implantable Medical Device under the AIMD  In-Vitro Diagnostic medical device under the IVDD |
| *D.2 Country for which Certificate of Free Sale is issued:*  Click or tap here to enter text. |

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| *D.3 Devices to be included on the Certificate of Free Sale* | | | |
| Product Code: | Device Registration Number: | Description: | UDI-DI: |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

**Section E: documentation to be submitted**

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| Tick as applicable:  Declaration/s of Conformity for medical devices registered in this application Notified Body Certificates for relevant device/s  Instructions For Use  Labelling of the device (outer pack/label)  For Authorised Representatives: Notarised copy of the letter of designation  Copy of the Malta Business Registry Certificate of Company Registration  If any devices include materials for manufacture which are from animal origin (excluding devices which contain material of animal origin which are externally applied and are not placed in contact of broken skin), kindly attach document which includes details of device, material, animal source and country of origin. |

***\* 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. |
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| Position: | Click or tap here to enter text. |
| Signature: |  |
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| Date: | Click or tap to enter a date. |
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