MALTA MEDICINES AUTHORITY

For office use only: Medical Device Registration Form received on:

Medical Device Registration Form Reference No.

MT-MDF03

Application Form for Medical Device Registration to place Medical Devices on the EU Market

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

Refer to the *Guidance for Application for Medical Devices Registration to place Medical Devices on the EU Market* 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.

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SECTION A: APPLICATION INTRODUCTION

A.1 Date of Application (dd/mm/yyyy): *Applicant Name & Surname:* *Applicant Email Address:* *Applicant Contact Number:*
A.2 Organisation Status (tick as applicable): ☐ Manufacturer (fill in Section B) ☐ Authorised Representative (fill in Sections B & C)

SECTION B: MANUFACTURER: CONTACT DETAILS

Organisation Name:	Telephone Number:
Address:	Contact Name:
	Job Title:
	Email address:
If Organisation is registered with the Authority, quote reference number	

SECTION C: AUTHORISED REPRESENTATIVE CONTACT DETAILS

Organisation Name:	Telephone Number:
Address:	Contact Name:
	Job Title:
	Email address:
If Organisation is registered with the Authority, quote reference number	

SECTION D: MEDICAL DEVICE DETAILS

Section D to be completed separately for EACH medical device product. One application form must be completed per DoC.

D.1 Medical Device Registration Type (tick as applicable):

☐ First Registration of Medical Device (Proceed to Section D.2)

☐ Amending Registration of Medical Device:

Quote Medical Device Registration No.

Tick as appropriate:

☐ Withdraw Medical Device

☐ Revise Medical Device Details

D.2 Medical Device details (other than IVD):

D.2.1 Classification of Medical Device, other than IVD:

☐ Class I

☐ Custom-made devices

☐ System or Procedure Packs

☐ Other Medical Device*

(* this is reserved for sterilisation companies who may, in addition to the above categories of devices, sterilise other CE marked devices for placing on the market under own name).

D.2.2 Additional information for Medical Device, other than IVD

- Is device sterile? ☐ YES ☐ NO

If yes:

Quote Notified Body Number:

- Does the device have a measuring function? ☐ YES ☐ NO

If yes:

Quote Notified Body Number:

D.3 IVD details:

D.3.1 Classification of IVD:

☐ Device of List A

☐ Device of List B

☐ Device for self-testing (other than List B)

☐ All other IVDs

D.3.2 Notified body number (if applicable):

Quote Notified Body Number:

D.4 Nomenclature

For ALL Medical Devices, including IVDs

Device GMDN Code:

D.5 Additional Device Details
D.5.1 *For ALL Medical Devices, including IVDs* Trade Name: Generic Name: Intended Use:

SECTION E: 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.*

Additional documentation

Attached is/are the Declaration/s of Conformity (DoC) for the medical device/s registered in this application. ☐

For Authorised Representatives: I have provided evidence by attaching a notarised copy of the letter of designation. ☐

For devices which require a Notified Body: I have provided a copy of the relevant CE certification. ☐

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. ☐

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: