MALTA MEDICINES AUTHORITY

For office use only: Medical Device Registration Form received on: ___ / ___ / _____

Medical Device Registration Form Reference No. _____

MT-MDF03

Application Form for Revision or Withdrawal of Medical Device Registration

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

Refer to the GL-MDF03 *Guidance for Application for Medical Devices Registration to place Medical Devices on the EU Market* and GL-MDF07 *Guidance on fees in relation to Medical Devices*.

Guidelines are available on the Malta Medicines Authority Website www.medicinesauthority.gov.mt/medicaldevices.

02/2025

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www.medicinesauthority.gov.mt

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:
Malta Medicines Authority Organisation Registration Number:	
Single Registration Number:	

SECTION C: AUTHORISED REPRESENTATIVE CONTACT DETAILS

Organisation Name:	Telephone Number:
Address:	Contact Name:
	Job Title:
	Email address:
Malta Medicines Authority Organisation Registration Number:	
Single Registration Number:	

SECTION D: MEDICAL DEVICE DETAILS

If more than one device needs to be entered, you are requested to fill in the MT-MDF03 Medical Device Revision or Withdrawal excel sheet and attach it to the application.

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

☐ Withdraw Medical Device

☐ Revise Medical Device Details

Quote Medical Device Registration No.

D.2 Nomenclature
For ALL Medical Devices, including IVDs Device GMDN Code: Device EMDN Code:

D.3 Additional Device Details
D.3 *For ALL Medical Devices, including IVDs* Trade Name: Generic Name: Intended Use:

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 - in case of Revision
- ☐ Labelling of the device – in case of Revision
- ☐ For Authorised Representatives: Copy of the letter of designation
- ☐ Details and justification in case of Revision

**** 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.*

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: