MALTA MEDICINES AUTHORITY

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

Medical Device Registration Form Reference No.

MT-MDF22

Application for Customs Documentation and Product Compliance Evaluation

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

Refer to GL-MDF7 *Guidance on fees in relation to Medical Devices*.

Guidance and Application Form are available on the Malta Medicines Authority website www.medicinesauthority.gov.mt.

July 2024

Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000
info.medicinesauthority@gov.mt | (+356) 23 439 000
www.medicinesauthority.gov.mt

SECTION A: APPLICATION INTRODUCTION

Date of Application (dd/mm/yyyy): *Applicant Name & Surname:* *Applicant Email Address:* *Applicant Contact Number:*

SECTION B: IMPORTER 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: 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 D: AUTHORISED REPRESENTATIVE CONTACT DETAILS

*** The Authorised Representative should be included in all correspondence related to this application.**

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

SECTION E: MEDICAL DEVICE / IN-VITRO DIAGNOSTIC DETAILS

Catalogue Number:
UDI-DI:
Trade Name:
Generic Name:
Intended Use:

SECTION F: 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 (outer pack/label)
- ☐ Photo of the shipment received at customs
- ☐ Shipment documentation
- ☐ Proof of Payment attached

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

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: