MALTA MEDICINES AUTHORITY

For office use only: Medical Device CFS Application Form received on:

CFS Form Reference No.:

CFS 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 the *Guidance for Application for Certificates of Free Sale for Medical Devices* 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.

June / 2023

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

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

SECTION B: MANUFACTURER DETAILS

Organisation Name:	Telephone Number:
Address:	Contact Name:
	Job Title:
	Email address:
Malta Business Registry Company Number	

SECTION C: AUTHORISED REPRESENTATIVE DETAILS

Organisation Name:	Telephone Number:
Address:	Contact Name:
	Job Title:
	Email address:
Malta Business Registry Company Number	

SECTION D: INFORMATION ON CERTIFICATE OF FREE SALE

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

☐ Active Implantable Medical Device (AIMD)

☐ In-Vitro Diagnostic medical device (IVD)

☐ Other medical devices

D.2 Devices to be included on the Certificate of Free Sale

Product Code:	Device Registration Number:	Description:	UDI-DI:

SECTION E: DOCUMENTS

Tick as applicable:

☐ Proof of Manufacture (Notarised Document)

☐ Notified Body Certificates for relevant device/s

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.*

Additional documentation

I have attached a copy of the Malta Business Registry Certificate of Company Registration. ☐

I have attached Mock-Ups of the label, packaging and instructions of use. ☐

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

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: