MALTA MEDICINES AUTHORITY

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

Medical Device Approval Form Reference No.

MT-MDF13

Application Form for MDR Article 97 for a Derogation from the Conformity Assessment Procedures of Medical Devices

The application is valid when submitted with the relevant documents. Filled in applications should be forwarded to mdforms.medicinesauthority@gov.mt.

Refer to GL-MDF07 Guidance on fees in relation to Medical Devices. Guidance and Application Form are available on the Malta Medicines Authority websitehttps://medicinesauthority.gov.mt/.

September / 2023

SECTION A: APPLICATION DETAILS

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 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 DETAILS

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

SECTION D: INFORMATION ABOUT THE PRODUCT

Name of device(s) for which the derogation is being requested as per DOC:
Catalogue Number of device
Intended Purpose of device
Specify the period for which the derogation is being requested.
Specify reason for which derogation is being requested.
Is the medical device(s) concerned of vital importance relating to public health or patient safety or health? ☐ Yes ☐ No
Reason:
Is there a lack of suitable substitutes available on the market? ☐ Yes ☐ No
Are there any indications in the technical dossier, or from vigilance or market surveillance activities, concerning devices of previous generations or with similar characteristics, that the device could be harmful for patient health or safety or public health? ☐ Yes ☐ No If yes, please specify.

SECTION E: MANDATORY DOCUMENTS

Supporting documentation in attachment:

- ☐ Declaration of Conformity (DoC)
- ☐ Instructions for Use (IFU)
- ☐ Labelling of Device *(mock-up or images of full product labelling required)*
- ☐ CE Certificate
- ☐ Confirmation letter by notified body that application for MDR certification has been accepted and contract with manufacturer signed, including expected timeline of conformity assessment procedure.
- ☐ Document(s) containing vigilance or market surveillance data to prove that the device(s) can be used in a safe and appropriate way for the patient and other person(s) involved. The documentation should also contain information that supports a positive benefit/risk balance.
- ☐ Proof of registration of device in accordance with national requirements
- ☐ Short description from which date and for which reason the device is not or will not be in compliance with MDR
- ☐ Documentation regarding manufacturer's assessment of changes including their potential significance
- ☐ MDR QMS certificate or confirmation by manufacturer with supporting documents including valid ISO 13485 certificate
- ☐ Confirmation by manufacturer for continuous application of MDR requirements in relation to PMS, vigilance and market surveillance including commitment by manufacturer to proactively inform the Competent Authority about any safety related corrective or preventive actions

SECTION F: DETAILS OF PAYMENT

- ☐ Proof of Payment attached (Standard Payment)

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:

Name & Surname:

Position:

Signature:

Date: