MALTA MEDICINES AUTHORITY

***For office use only:***

MD/IVD-Application Form Risk Classification: received on: ___ / ___ / _____

MD/IVD-Application Form Risk Classification: Reference No. _____

**MT-MDF20**

**Application Form for Medical Device / In-Vitro Diagnostic**

**Evaluation of Risk Classification**

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

**Relevant correspondence should reach the Authority via email address mdforms.medicinesauthority@gov.mt.**

**Refer to GL-MDF07 Guidance on fees in relation to Medical Devices. Guidance is available on the Malta Medicines Authority website www.medicinesauthority.gov.mt.**

November 2024

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www.medicinesauthority.gov.mt

## SECTION A: APPLICATION INTRODUCTION

| |
|---|
| *Date of Application* (dd/mm/yyyy):<br><br>*Applicant Name & Surname:*<br><br>*Applicant Email Address:*<br><br>*Applicant Contact Number:*<br><br>Dispute between Manufacturer and Notified Body<br>Yes<br><br>No |

## SECTION B: MANUFACTURER CONTACT DETAILS

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

## SECTION C: AUTHORISED REPRESENTATIVE CONTACT DETAILS

*** If applicable, the Authorised Representative should be included in all correspondence related to this application.**

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

## SECTION D: MEDICAL DEVICE / IN-VITRO DIAGNOSTIC DETAILS

| |
|---|
| Trade Name: |
| Generic Name: |
| Intended Use: |
| Proposed Risk Class by Manufacturer: |
| Proposed Risk Class by Notified Body (if applicable): |

## SECTION E: DOCUMENTATION TO BE SUBMITTED

- ☐ Declaration of Conformity (if available)
- ☐ Labelling of the device
- ☐ Instructions For Use (IFU)
- ☐ Documents with rationale of proposed risk classification:
  - ☐ Report of the Manufacturer
  - ☐ Report of the Notified Body (if applicable)

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

## SECTION F: DETAILS OF PAYMENT

- ☐ 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: