MALTA MEDICINES AUTHORITY

For office use only: Medical Device Notification Form-Local received on: ___ / ___ / ____

Medical Device Notification Form Reference No.: _____

MT-MDF05

Application Form for Notification

of Medical Devices Made Available on the Local Market

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

Refer to the GL-MDF05 *Guidance for Application for Medical Device Notification for Medical Devices Made Available on the Local Market* and GL-MDF07 *Guidance on fees in relation to Medical Devices* available on the Malta Medicines Authority website https://medicinesauthority.gov.mt/medicaldevices.

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 Organisation Details
Organisation Name: Organisation Registration Number:

SECTION B: MANUFACTURER CONTACT DETAILS

Organisation Name:	Email address:
Address:	
Single Registration Number:	

SECTION C: AUTHORISED REPRESENTATIVE CONTACT DETAILS

Organisation Name:	Email address:
Address:	
Single Registration Number:	

SECTION D: SOURCE COUNTRY SUPPLIER DETAILS

Organisation Name:
Address:

SECTION E: MEDICAL DEVICE DETAILS

E.1 Notification Type (tick as applicable):

☐ First Notification of Medical Device

☐ Amending Notification of Medical Device

☐ Withdraw Medical Device

Application reference number: _____

E.2 Device Notification Sheet

List all devices. Refer to definition of ***variant*** in GL-MDF05 *Guidance for Application for Notification of Medical Devices Made Available on the Local Market*.

To be filled in embedded sheet

Device Notification.xlsx

SECTION F: DETAILS OF PAYMENT

☐ Proof of Payment attached (Standard fee)

☐ Proof of Payment attached (Fast-track fee)

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, , 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

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

Self-Declaration for Medical Device Notification/s

I, the undersigned hereby declare that the medical devices being made available on the Maltese market by the legal person / organisation hereunder, comply with all applicable EU and national legislations.

I also bind myself to immediately notify the Malta Medicines Authority on email address mdforms.medicinesauthority@gov.mt if any of the medical devices made available by the legal person / organisation hereunder are recalled or withdrawn from the market. All the information concerning the reason for recall or withdrawal, the affected products, and any actions taken to address the issue shall be provided in written correspondence, such as electronic mail.

This self-declaration is being made with the full understanding of our legal obligations as an importer and/or distributor of medical devices in Malta in accordance with EU and national legislations.

Organisation Name:

Contact Name:

Role: Medical Device Registered Person (MDRP)

Email address:

Signature:

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: