



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>.

August 2023

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SECTION A: APPLICATION INTRODUCTION

<p><i>A.1 Date of Application (dd/mm/yyyy):</i></p> <p><i>Applicant Name & Surname:</i></p> <p><i>Applicant Email Address:</i></p> <p><i>Applicant Contact Number:</i></p>
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<p><i>A.2 Applicant Organisation Details</i></p>
<p>Organisation Name:</p>
<p>Organisation Registration Number:</p>

SECTION B: MANUFACTURER CONTACT DETAILS

Organisation Name:	Telephone Number:
Address:	Contact Name:
	Job Title:
	Email address:

SECTION C: AUTHORISED REPRESENTATIVE CONTACT DETAILS

Organisation Name:	Telephone Number:
Address:	Contact Name:
	Job Title:
	Email address:

SECTION D: MEDICAL DEVICE DETAILS

D.1 Notification Type (tick as applicable):

- First Notification of Medical Device
- Amending Notification of Medical Device:

Tick below as appropriate:

- Revise Medical Device Details
- Withdraw Medical Device

D.2 Device Notification Sheet

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

Excel sheet to be filled can be found in attachments.

SECTION E: 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.

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: