For office use only:

Use of a Non-CE Marked Med Dev-Request Form: received on:

Use of a Non-CE Marked Med Dev-Request Form: Reference No.

MT-MDF04

Request Form for the Use of a Non-CE Marked Medical Device in Malta

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 and Application Form are available on the Malta Medicines Authority website www.medicinesauthority.gov.mt.

June 2023

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SECTION A: APPLICATION INTRODUCTION

Date of Application (dd/mm/yyyy):
Applicant Name & Surname:
Applicant Email Address:
Applicant Contact Number:

SECTION B: APPLICATION TYPE

☐ Patient-named basis application request; Proceed to Section C

☐ Hospital/clinic application request (Departmental use); Proceed to Section D

SECTION C: PATIENT DETAILS

Name:	Surname:
I.D. Number:	Date of Birth:
Medical Condition of Patient:	
Patient/Legal Guardian Consent I am aware that the medical device has no CE mark and my healthcare practitioner has explained any possible implications involved. **Name and Surname:** **Signature:** **Date:**	

SECTION D: DETAILS OF MEDICAL SPECIALIST

Name of Medical Specialist:
Specialisation:
Registration Number:
Email Address:
Telephone Number:

SECTION E: HOSPITAL/CLINIC DETAILS

Hospital / Clinic Name & Address:
Department Name:
Email Address:
Telephone Number:

SECTION F: MEDICAL DEVICE DETAILS

Product Name:	Catalogue Number:
Intended Use:	
Why is the non-CE marked medical device being requested for this patient?	
Is an equivalent CE marked medical device available on the Union market? ☐ YES ☐ NO	
If yes, explain what differentiates this non-CE marked device from equivalent CE marked devices	
Country and Authority granting approval:	

SECTION G: CLINICAL BENEFIT-RISK ASSESSMENT

Explain how, for the declared intended use, the potential benefits in using this medical device outweigh the potential risks to the patient/s in using it
Indicate the consequences, if any, to the patient/s' condition/s, if the medical device is not authorised in this situation

SECTION H: MANUFACTURER DETAILS

Organisation Name:
Address:
Contact Name:
Email Address:
Telephone Number:

SECTION I: CONFORMITY ASSESSMENT BODY DETAILS

Entity Name:
Address:
Contact Name:
Email Address:
Telephone Number:

SECTION J: SUPPLIER (LOCAL) DETAILS

Supplier Name:	
Address:	
Contact Name:	
Email Address:	
Telephone Number:	
Quote organisation registration reference number, issued by the Malta Medicines Authority	

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

☐ Documents attached verifying the performance on the non-CE marked device.

☐ 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.

Medical Specialist Declaration Form

I, , hereby declare that the request is being submitted in the interest of public health.

Medical Specialist Signature: Date:

Full Name: Position / Title:

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:

Superintendence of Public Health Recommendation

The above-mentioned device is approved for use by the department listed in Section E, for a period of until .

Further conditions (if applicable):

The approval can be revoked based on any reports on relevant safety and performance issues.

Superintendent of Public Health	***Date (DD/MM/YYYY)***