For office use only:

Application for Pre-Submission Meeting Request received on:

Application for Pre-Submission Meeting Request Reference No.

MT-MDF14

Application for Pre-Submission Meeting Request for Clinical Investigations/Performance Studies

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

Relevant correspondence should reach the Malta Medicines Authority via Email address mdforms.medicinesauthority@gov.mt.

Refer to GL-MDF13 Guidance for Application / Notification for Clinical Investigations under Regulation (EU) 2017/745 on Medical Devices and GL-MDF07 Guidance on Fees in relation to Medical Devices, which available on the Malta Medicines Authority website www.medicinesauthority.gov.mt.

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info.medicinesauthority@gov.mt | (+356) 23 439 000
www.medicinesauthority.gov.mt

SECTION A: APPLICATION INTRODUCTION & APPLICANT DETAILS

A.1 Date of Application (dd/mm/yyyy): *Name & Surname:* *Email Address:* *Contact Number:*
A.2 Organisation Status (tick as applicable): ☐ Manufacturer (fill in Section B) ☐ Authorised Representative (fill in Sections B & C)

SECTION B: MANUFACTURER CONTACT 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 CONTACT DETAILS

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

SECTION D: PRODUCT INFORMATION

D.1 Name of product:
D.2 Generic name of product:
D.3 Catalogue number (where applicable):
D.4 Product intended purpose:
D.5 Regulation applied (Product falls under the): ☐ Medical Device Regulation (EU) 2017/745 (MDR) ☐ In-Vitro Medical Device Regulation (EU) 2017/746 (IVDR)
D.6 Class of Proposed Medical Device
D.7 Regulatory status of the proposed Medical Device ☐ Non-CE-marked Medical Device ☐ CE marked Medical Device to be used within its intended purpose ☐ CE marked Medical Device to be used outside the scope of its intended purpose ☐ Other (Specify):

SECTION E: ADDITONAL INFORMATION REQUIRED

E.1 Will this investigation / study be conducted in another country? ☐ Yes ☐ No Please specify
E.2 Provide the planned timelines for this investigation / study
E.3 List any queries to be discussed during the meeting:
E.4 Provide any relevant documentation

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, 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: