For office use only:

Modification of performance study under Regulation (EU) 2017/746 on in vitro diagnostic medical devices received on

Modification of performance study under Regulation (EU) 2017/746 on in vitro diagnostic medical devices Reference No.

MT-MDF18

Performance Study – Notification for Modification of Performance Study under the In Vitro Diagnostic Regulation (EU) 2017/746

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

Refer to GL-MDF16 *Guidance for Notification for Modification of Performance Studies under the Regulation (EU) 2017/746* and Guidance on fees in relation to Medical Devices. Guidance and Application Form are available on the Malta Medicines Authority website www.medicinesauthority.gov.mt.

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www.medicinesauthority.gov.mt

SECTION A: NOTIFICATION INTRODUCTION

A.1 Date of Notification (dd/mm/yyyy): *Name & Surname:* *Email Address:* *Contact Number:*
A.2 Applicant (tick as applicable) ☐ Sponsor (within the Union): Fill in Section B ☐ Legal Representative (when Sponsor is outside the Union): Fill in Section C

SECTION B: SPONSOR 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: LEGAL 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: INVESTIGATOR CONTACT DETAILS

Name:	Telephone Number:
Job Title:	
Email address:	
Healthcare Institution:	

SECTION E: IDENTIFICATION OF THE PERFORMANCE STUDY

D.1 MMA Reference No.: *Performance Study ID:* *Performance Study Title:* *Date of previous authorisation/notification:*
D.2 Performance Study Plan (PSP) details: *PSP code:* *PSP version no.:* *PSP date:*

SECTION F: INFORMATION ON THE DEVICE

E.1 Name of Device
E.2 Model of Device
E.3 Classification of Medical Device
E.4 Description of Device including its intended purpose
E.5 Are there any changes or modifications in relation to the device or its components since the previous application/notification to the Malta Medicines Authority? ☐ *Yes (If yes, provide a rationale and description of these changes)* ☐ *No*

SECTION G: NOTIFICATION FORM (EU)

Refer to the MDCG 2022-20 guidance in the In Vitro Diagnostic medical devices (IVD) section.

Documentation in attachment:

☐ Filled in relevant forms

☐ Supporting documents

SECTION H: DETAILS OF PAYMENT

☐ Proof of Payment attached

SECTION I: 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: