

MDCG 2020-19

Performance study application/notification documents under Regulation (EU) 2017/746

December 2022

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/746. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

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Table of contents

1 ACRONYMS..... 3

2 INTRODUCTION 4

3 ANNEX – TEMPLATES 5

1 Acronyms

- EUDAMED** European database on medical devices
- GSPR** General safety and performance requirements
- NCA** National competent authority
- PMPF** Post-market performance follow-up
- REC** Research ethics committee

2 Introduction

The sponsor of a performance study is required to submit an application/notification¹ to the Member State(s) in which a performance study is to be conducted, accompanied by the documentation referred to in Chapter I of Annex XIV of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (the IVDR). The application/notification must be submitted by means of the electronic system referred to in Article 69 of the IVDR.

In the absence of the European database on medical devices (EUDAMED), a series of performance study application/notification documents have been created to support performance study procedures with respect to the IVDR.

These documents include:

- Performance study – application/notification form under the IVDR
- Addendum to the performance study application/notification form for:
 - Additional performance device(s) (section 3)
 - Additional comparator device(s) (section 4)
 - Additional site(s) (section 5)
- Performance study supporting documents - Appendix of documents to attach
- Checklist of general safety and performance requirements, standards, common specifications and scientific opinions

Insofar as possible, the performance study application/notification form includes the same data fields as the EUDAMED system in development.

For further guidance with respect to the application of certain IVDR provisions in the absence of EUDAMED please see MDCG 2022-12². In the absence of EUDAMED, the Union-wide unique single identification number for a performance study, to be used for all relevant communication in relation to that performance study, will be the CIV-ID which can be generated in Eudamed2, the electronic system which supports the medical device Directives.

Use of templates

These documents are intended to be facilitative and their use by the competent authorities and sponsors is encouraged, however it is important to check with the individual Member State in which the performance study is planned to be conducted for any specific national requirements. It is planned that these templates will be withdrawn once the EUDAMED module for performance studies is fully functional. Further operational guidance with respect to the use of the templates may be provided in due course.

¹ Performance study application (IVDR Art. 66(1)), PMPF study notification (IVDR Art. 70(1)).

² [MDCG 2022-12](#) Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional (for Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices)

3 Annex – Templates

Title	Document
Performance study – application/notification form under Regulation (EU) 2017/746 on <i>in vitro</i> diagnostic medical devices	 A application form PS v1_0.pdf
Additional performance device(s) (section 3)	 B appendix application form PS v
Additional comparator device(s) (section 4)	 C appendix application form PS v
Additional site(s) (section 5)	 D appendix application form PS v
Performance study supporting documents – Appendix of documents to attach	 E appendix of documents to attach f
Checklist of general safety and performance requirements, standards, common specifications and scientific opinions	 F Checklist GSPR and list of standards for IV



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