MDCG 2022-19

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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1 Acronyms

EUDAMED European database on medical devices

GSPR General safety and performance requirements

NCA National competent authority

PMPF Post-market perfomance follow-up

REC Research ethics committee

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2 Introduction

The sponsor of a performance study is required to submit an application/notification[1] 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 2022-12[2]. 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 *in vitro* diagnostic medical devices	View document
Additional performance device(s) (section 3)	View document
Additional comparator device(s) (section 4)	View document
Additional site(s) (section 5)	View document
Performance study supporting documents – Appendix of documents to attach	View document
Checklist of general safety and performance requirements, standards, common specifications and scientific opinions	View document

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