

Performance study - application/notification form under *In Vitro* Diagnostic Medical Devices Regulation (IVDR)

Application/notification form version

Section 1: Performance study identification

1.1 Sponsor identification

Name:		
Address	Street name:	Street number:
	Postal code:	City:
	Country:	
Telephone number:		
Email:		

Contact person of the sponsor

First name:
Last name:
Telephone number:
Email:

Sponsor's legal representative identification

Do you have a legal representative?
Yes No
If yes, complete the information related to the legal representative (section 1.2)

1.2 Legal representative identification

Organisation name:		
Address	Street name:	Street number:
	Postal code:	City:
	Country:	
Telephone number:		
Email:		

Contact person of the legal representative

First name:
Last name:
Telephone number:
Email:

Contact person for the performance study

Same as contact person of sponsor
Same as contact person of legal representative
Other
If you selected other, please fill in the section below related to the other contact person for this performance study.

Other contact person for the performance study

First name:		
Last name:		
Address	Street name:	Street number:
	Postal code:	City:
	Country:	
Telephone number:		
Email:		

1.3 Performance study type

Select the appropriate regulatory pathway for the application:

Performance study application (IVDR Art. 58 (1&2))

PMPF study notification (IVDR Art. 70(1))

Performance study notification involving companion diagnostics using left-over samples only. (IVDR Art. 58(2))

1.4 Submission type

First submission in the EEA, if available, provide the performance study ID (PS-ID)

First submission at the national level (performance study has been already submitted in EEA). In this case, please provide the CIV-ID

Resubmission. Please provide the CIV-ID

1.5 Participating countries within the EU/EEA/UK (Northern Ireland), Türkiye and Switzerland

Select the participating countries for the performance study

1.6 Participating countries outside EU/EEA/UK (Northern Ireland), Turkey and Switzerland

If this study is part of a multi-site performance study outside the EU/EEA/UK, please provide a list of all participating non EU/EEA countries.

1.7 Performance study plan (PSP)

PSP code:

PSP version:

PSP date:

1.8 Performance study title

Full title:

Short title:

Title for lay people:

Section 2: Performance study description

2.1 Performance study characteristics

Surgically invasive sample-taking is done only for the purpose of the performance study

In the following case, does the specimen collection represent a major clinical risk to the subject?

Yes	No
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Please provide a justification of your answer:

Interventional clinical performance study as defined in point (46) of article 2 from IVDR
Conduct of the study involves additional invasive procedures or other risks for the subjects of the study
Study involving companion diagnostics

In the following case, will only left-over samples be used in the study?

Yes	No
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PMPF study involving additional procedures that are burdensome or invasive, compared to those performed under the normal conditions of use
Other(s) characteristic(s):

2.2 Development stage in the framework of European regulation.

Pre-market stage

Post-market stage

2.3 Objectives and endpoint

Primary objective(s):

Secondary objective(s):

Other objective(s):

Primary endpoint(s):

Secondary endpoint(s):

Other endpoint(s):

2.4 Synopsis of the performance study

Overall synopsis:

2.5 Planned number of subjects/samples

Geographic area	Subjects	Samples
In Europe:		
In Asia:		
In Africa:		
In North America:		
In South America:		
In Oceania:		
Total planned number of subjects/samples:		

2.6 Duration of performance study

Estimated start date:

Estimated end date:

2.7 Population**2.7.1 Medical condition**

Is there an associated medical condition?

Yes

No

Is the medical condition considered to be rare?

Yes

No

2.7.2 Gender of subjects

Female

Male

Other

2.7.3 Inclusion criteria

2.7.4 Exclusion criteria

2.7.5 Type of subjects that will be recruited for the performance study

Healthy	Patients	Vulnerable population
Minors	Pregnant women	Breastfeeding women
Patients in emergency situations	Incapacitated subjects	
Other (please specify):		

2.7.6 Age range of the participants to be included in the performance study

In utero
Newborns (from 0 to 27 days)
Infants and toddlers (from 28 days to 23 months)
Children (from 2 to 5 years)
Children (from 6 to 11 years)
Adolescents (from 12 to 17 years)
Adults (from 18 to 84 years)
Elderly (from 85 years)

2.8 Scope of the device for performance study

2.8.1 Combined study Medical Device/In Vitro Diagnostic Medical Device?

Yes	No
If yes, please provide the related identification number of the clinical study	

2.8.2 Is the application submitted in parallel with an application for a clinical trial on medicinal products?

Yes	No
If yes, please provide the EU Clinical Trial Number:	

2.9 Coordinating investigator

First name:		
Last name:		
Address	Street name:	Street number:
	Postal code:	City:
	Country:	
Telephone number:		
Email:		

Section 3: Device for performance study

3.1 Performance study

3.1.1 Device purposes

Physiological process or state
Pathological process or state
Congenital physical impairments
Congenital mental impairments
Predisposition to a medical condition or a disease
To determine the safety with potential recipients
To determine compatibility with potential recipients
To predict treatment response or reactions
To define therapeutic measures
Monitoring therapeutic measures
Specimen receptacle

3.1.2 Device type

Intended for self-testing	Calibrator
Intended for near-patient testing	Control material
Companion diagnostics	
Reagent	
Professional use	
Instrument	
Kit	
Sterile	
Software	

3.1.3 Device identifiers

Generic denomination:			
Device trade name:		Model:	
Device name:			
European Medical Device Nomenclature (weblink):			
Medical device classification: (MDCG 2020-16)			

Classification rule:

Device description:

Intended purpose:

If the device for performance study is a companion diagnostic, please provide the medicinal substance(s) name(s) for which the device for performance study is referring to:

Does the device include tissues, cells and substances of human, animal or microbial origin?

Yes

No

If yes, please provide further information on the tissues, cells, substances of human, animal or microbial origin:

CE marked device will be used? Yes No If yes, please provide the information in the box below.
To what extent is the intended purpose of the device in the performance study covered by the CE-mark? CE marked device will be used outside the scope of its CE mark CE marked device will be used within the scope of its CE mark and no additional procedures are foreseen in the performance study CE marked device will be used within the scope of its CE mark, but additional procedures are foreseen in the performance study Are those additional procedures considered to be burdensome and/or invasive? Yes No Please, comment why do you consider as such? Information related to the Notified body involved, if applicable: Notified body number: Notified body name:

3.2 Previous performance study

Has the device for performance study been investigated within the EU previously? Yes No If yes, please provide the relevant reference number(s) (such as SIN, CIV-ID, other reference(s)) of the previous performance study.
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3.3 Scientific opinion/view

Has the device for performance study been subject to a national scientific opinion or Expert Panel view? Yes No If yes, please provide the relevant reference to this opinion:
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3.4 Manufacturer of the device for performance study

Is the manufacturer the same as the sponsor?

Yes No

If no, please fill in the requested information in section 3.4.1 and 3.4.2

3.4.1 Manufacturer information

Organisation name:

Address

Street name:

Street number:

Postal code:

City:

Country:

Telephone number:

Email:

Contact person of the manufacturer

First name:

Last name:

Telephone number:

Email:

3.4.2 Authorized representative

Organisation name:		
Address	Street name:	Street number:
	Postal code:	City:
	Country:	
Telephone number:		
Email:		

Contact person of the authorized representative

First name:
Last name:
Telephone number:
Email:

Additional devices for performance study could be added by using a duplicated section 3, in appendix to this application form.

Section 4: Comparator

4.1 Applicability of section 4

Is there a comparator included in the performance study?

Yes

No

If yes, the section form 4.2 needs to be completed.

4.2 Type of comparator

In Vitro Diagnostic Medical Device

Other, please specify:

4.2.1 In Vitro Diagnostic Medical Device as comparator

Is the comparator in vitro medical device CE marked?

Yes

No

If yes, will the CE marked comparator in vitro medical device be used in the performance study within the scope of its CE mark?

Yes

No

Generic denomination:

Device trade name:

Model:

Device name:

European Medical Device Nomenclature (weblink):

Medical device classification:

Classification rule:

Device description:

Intended purpose:

Does the comparator device include tissues, cells, and substances of animal, human or microbial origin?

Yes

No

If yes, please provide further information on the tissues, cells, substances of human, animal or microbial origin:

Additional comparator for performance could be added by using a duplicated section 3, in appendix to this application form.

Section 5: National information

5.1 Study site information

Please provide the list of sites taking part in the study performance

Name of institution	Site address	Investigator attached to this site	Contact information of investigators

Additional sites could be added by using a duplicated section 5.1, in appendix to this application form

5.2 Ethics committee information

Select the applicable option:

Ethics committee opinion available, in the following option,

please select the Ethics committee opinion : Positive Negative

Ethics committee opinion under review

Ethics committee opinion is not mandatory before submission to the competent authority

If an ethics committee has to be selected by the sponsor before submission, please provide the ethics committee information's below.

Organisation name:

Address	Street name:	Street number:
	Postal code:	City:
	Country:	

Email:

Ethics committee statement:

I understand that the Competent Authority may contact the Ethics Committee that is assessing or has assessed the application

5.3 Status of the study sponsor

Is the sponsor considered as commercial according to national legislation?

Yes

No

5.4 Expected number of subjects recruited within the Member State

How many subjects are expected to be recruited into the study in the Member State you are applying to?

Please use the template named “appendix of documents to attach” to identify clearly which documents are being attached to this application/notification.

I hereby certify that the information and documentation submitted with this application/notification is correct in detail and all the information requested has been supplied. The device for performance study complies with the applicable general safety and performance requirements, apart from those covered by the study and that every precaution has been taken to protect the health and safety of the patient and/or user.

I confirm that all the study performance information collected for this application, has been done in compliance with the European data protection legislation (GDPR)

Date:
(mm/dd/yy)

Name:

Position:



医课汇
公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



hlongmed.com
医疗器械咨询服务
MEDICAL DEVICE
CONSULTING
SERVICES



医课培训平台
医疗器械任职培训
WEB TRAINING
CENTER



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医疗器械知识平台
KNOWLEDG
ECENTEROF
MEDICAL DEVICE



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ECENTEROF MEDICAL
DEVICE