

# 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:



**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:		
<b>Total planned number of subjects/samples:</b>		

**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

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#### 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.

### **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:

### **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:**

<b>Address</b>	<b>Street name:</b>	<b>Street number:</b>
	<b>Postal code:</b>	<b>City:</b>
	<b>Country:</b>	

**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?
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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:**