



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

**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**

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

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

<p>Select the appropriate regulatory pathway for the application:</p> <p>Performance study application (IVDR Art. 58 (1&amp;2))</p> <p>PMPF study notification (IVDR Art. 70(1))</p> <p>Performance study notification involving companion diagnostics using left-over samples only. (IVDR Art. 58(2))</p>
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### 1.4 Submission type

<p>First submission in the EEA, if available, provide the performance study ID (PS-ID)</p> <p>First submission at the national level (performance study has been already submitted in EEA). In this case, please provide the CIV-ID</p> <p>Resubmission. Please provide the CIV-ID</p>
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### 1.5 Participating countries within the EU/EEA/UK (Northern Ireland), Türkiye and Switzerland

Select the participating countries for the performance study

Belgium	Germany	Lithuania	Republic of Cyprus
Bulgaria	Greece	Luxembourg	Romania
Croatia	Hungary	Malta	Slovakia
Czech Republic	Iceland	Netherlands	Slovenia
Denmark	Ireland	Northern Ireland	Spain
Estonia	Italy	Norway	Sweden
Finland	Latvia	Poland	Switzerland
France	Liechtenstein	Portugal	Türkiye

### 1.6 Participating countries outside EU/EEA/UK (Northern Ireland), Türkiye 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

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

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 North America:		
In South America:		
In Oceania:		
Total planned number of subjects/samples:		

## 2.6 Duration of performance study

<p>Estimated start date:</p> <p>Estimated end date:</p>
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## 2.7 Population

### 2.7.1 Medical condition

<p>Is there an associated medical condition?</p> <p>Yes</p> <p>No</p>
<p>Is there medical condition considered to be rare?</p> <p>Yes</p> <p>No</p>

### 2.7.2 Gender of subjects

Female	Male	Other
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### 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 in emergency situations	Pregnant women	Vulnerable population
Minors	Patients	Incapacitated subjects	Breastfeeding women
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	Kit
Intended for near-patient testing	Sterile
Companion diagnostics	Software
Reagent	Calibrator
Professional use	Control material
Instrument	

##### 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

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

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

<p>Is the manufacturer the same as the sponsor?</p> <p>Yes</p> <p>No</p> <p>If no, please fill in the requested information in section 3.4.1 and 3.4.2</p>
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#### 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

<p>Is there a comparator included in the performance study?</p> <p>Yes</p> <p>No</p> <p>If yes, the section form 4.2 needs to be completed.</p>
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### 4.2 Type of comparator

<p>In Vitro Diagnostic Medical Device</p> <p>Other, please specify:</p>
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#### 4.2.1 In Vitro Diagnostic Medical Device as comparator

<p>Is the comparator in vitro medical device CE marked?</p> <p>Yes</p> <p>No</p> <p>If yes, will the CE marked comparator in vitro medical device be used in the performance study within the scope of its CE mark?</p> <p>Yes</p> <p>No</p>	
<p>Generic denomination:</p>	
<p>Device trade name:</p>	<p>Model:</p>
<p>Device name:</p>	

European Medical Device Nomenclature (weblink):
Medical device classification: (MDCG 2020-16)
Classification rule:
Device description:
Intended purpose:
<p>Does the comparator device include tissues, cells, and substances of animal, human or microbial origin?</p> <p>Yes</p> <p>No</p> <p>If yes, please provide further information on the tissues, cells, substances of human, animal or microbial origin:</p>

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

## 5.2 Ethics committee information

<p>Select the applicable option:</p> <p>Ethics committee opinion available, in the following option, please select the Ethics committee opinion:</p> <p>Positive</p> <p>Negative</p> <p>Ethics committee opinion under review</p> <p>Ethics committee opinion is not mandatory before submission to the competent authority</p> <p>If an ethics committee has to be selected by the sponsor before submission, please provide the ethics committee information's below.</p>	
Organisation name	
Address	
Street name	Street number
Postal code	City
Country	
Telephone number	Email
<p>Ethics committee statement:</p> <p>I understand that the Competent Authority may contact the Ethics Committee that is assessing or has assessed the application</p>	

## 5.3 Status of the study sponsor

<p>Is the sponsor considered as commercial according to national legislation?</p> <p>Yes</p> <p>No</p>
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#### 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).

Signature	
Name	Position
Date (mm/dd/yy)	