Performance study – application/notification form under *In Vitro* Diagnostic Medical Devices Regulation

Application/notification form version 0.9_BE

Section 1: Performance study identification

1.1 Sponsor identification

Name:			
Address	Street name:		Street number:
	Postal code:		City:
	Country:	Australia	
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:	Belgium	
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:	Belgium	
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

◯ First submission at the national level (performance study has been already submitted in EEA)

In this case, please provide the performance study ID (PS-ID) provided

◯ Resubmission

Please provide the PS-ID if already available

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

Select the participating countries for the performance study

Lithuania
Luxembourg
Malta
Netherlands
Northern Ireland
Norway
Poland
Portugal
Republic of Cyprus
Romania
Slovakia
Slovenia
Spain
Sweden
Turkey

1.6 Participating countries outside EU/EEA/UK

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.
- ☐ Interventional clinical performance study as defined in point (46) of Article 2.
- ☐ Conduct of the study involves additional invasive procedures or other risks for the subjects of the study.
- ☐ Study involving companion diagnostics.
- ☐ PMPF study involving additionnal procedures burdensome or invasive, to those performed under the normal conditions of use.
- ☐ Other(s) characteristic(s):

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2.3 Objectives and endpoints

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

In Europe:
In Asia:
In Africa:
In North America:
In South America:
In Oceania:
Total planned number of subjects/samples: 0

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 the performance study plans to recruit

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

2.7.6 Age range of the participants that the study performance plans to include

☐ In utero	☐ Adults (from 18 to 84 years)
☐ Newborns (from 0 to 27 days)	☐ Elderly (from 85 years)
☐ 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)	

2.8 Scope of the investigational device

2.8.1 Combined investigation 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: Australia	
Telephone number:		
Email:		

Section 3: Investigational device(s)

3.1 Performance study

3.1.1 Device purposes

- 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
- ☐ Intended for near-partient testing
- ☐ Companion diagnostics
- ☐ Reagent
- ☐ Professional testing
- ☐ 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:
- Class A
- Class B
- Class C
- Class D

Classification rule:
- Rule 4 - self-testing
- Rule 4 - near-patient testing
- Rule 5 - general laboratory use wiht no critical characteristics
- Rule 5 - specifically to be used for in vitro dianostic procedure
- Rule 5 - specimen receptacles
- Rule 6 - Other - no covered by rule 1 to 5
- Rule 7 - controls without a quantitative or qualitative assigned value

Device description:

Intended purpose:

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

Is the Investigational Device CE marked?

○ 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 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 this device been investigated in a performance study within the EU previously?

○ Yes ○ No

If yes, please provide the relevant reference number(s) (such as SIN, PS-ID, other reference(s)) of the previous performance study

3.3 Scientific opinion/view

Has the investigational/study device been subject to a national scientific view/opinion from an Expert Panel

○ Yes ○ No

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: Belgium	
Telephone number:		
Email:		

Contact person of the manufacturer

First name:
Last name:
Telephone number:
Email:

3.4.2 Authorised representative

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

Contact person of the authorised representative

First name:
Last name:
Telephone number:
Email:

Additional devices 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

- ◯ Therapy
- ◯ Placebo
- ◯ No treatment
- ◯ Medical device

4.2.1 Medical device or *In Vitro* Diagnostic Medical Device as comparator

Is the comparator medical device CE marked? ◯Yes ◯No

If yes, will the CE marked comparator 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 :

Device description:

Intended purpose:

Does the comparator device contain or incorporate medicinal substance(s)?

◯ Yes ◯ No

If yes, please provide the medicinal substance(s) name(s):

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

◯ Yes ◯ No

Additional comparators could be added by using a duplicated section 4, 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

○ 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: Belgium	
Telephone number:		
Email:		

5.3 Status of the study performance

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?

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 investigated *In Vitro* Diagnostic Medical Device 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)

Name:

Position: