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

3.1.3 Device identifiers

Generic denomination:			
Device trade name:		Model:	
Device name:			
European Medical Device Nomenclature (weblink):			
Medical device classification: (MDCG 2020-16)	Class A / Class B / Class C / Class D		

Classification rule:

Rule 3 - be used as companion diagnostics
Rule 3 - be used for disease staging, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation
Rule 3 - be used in screening, diagnosis, or staging of cancer
Rule 3 - detecting the presence in cerebrospinal fluid or blood of an infectious agent without a high or suspected high risk of propagation
Rule 3 - detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetu
Rule 3 - detecting the presence of, exposure to, a sexually transmitted agent
Rule 3 - determining infective disease status or immune status, where there is a risk that an erroneous result would lead to a patient management decision resulting in
Rule 3 - human genetic testing
Rule 3 - management of patients suffering from a life-threatening disease or condition
Rule 3 - monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient managemer
Rule 3 - pre-natal screening of women in order to determine their immune status towards transmissible agents
Rule 3 - screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabil
Rule 3 - screening for congenital disorders in the embryo or foetus
Rule 4 - near-patient testing
Rule 4 - self-testing
Rule 5 - general laboratory use with no critical characteristics
Rule 5 - specifically to be used for in vitro diagnostic procedure
Rule 5 - specimen receptacles
Rule 6 - Other - not covered by rule 1 to 5
Rule 7 - controls without a quantitative or qualitative assigned value

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:	Belgium	
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:	Belgium	
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.