

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



医课汇
公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



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MEDICAL DEVICE



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