LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

MREC
MEDICAL RESEARCH ETHICS COMMITTEES

Application form for the authorisation of performance studies of in vitro diagnostic medical devices

This is a joint Danish Medicines Agency (DKMA) and Medical Research Ethics Committees (MREC) performance study application form.

The application is to be submitted as **one e-mail to two recipients**;
DKMA: med-udstyr@dkma.dk and **MREC**: dketik@dketik.dk in order for both authorities to validate and assess the application within the same time frame.

The application form consists of the following elements:

- Performance study – application/notification form under the IVDR from MDCG guidance "*MDCG 2022-19 Performance study application/notification documents under Regulation (EU) 2017/746*".

- Performance study supporting documents – Appendix of documents to attach from "*MDCG 2022-19 Performance study application/notification documents under Regulation (EU) 2017/746*". For MREC specific document requirements please refer to the MREC website.

- DKMA invoice information.

- MREC invoice information.

If multiple performance study devices are included in the performance study, please copy and insert the document "Additional performance device(s) (section 3)" from the guidance MDCG 2022-19.

Note that this application form is solely to be used for performance studies under IVDR Article 58 (1+2). (the first tick-box in section *1.3 Performance study type*).

For PMPF studies and performance studies on companion diagnostics using left-over samples only, please contact DKMA and MREC.

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

Application/notification form version 1.0

Section 1: Performance study identification

1.1 Sponsor identification

Name:		
Address	Street name:	Street number:
	Postal code:	City:
	Country: Denmark	
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	
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

- Belgium
- Bulgaria
- Croatia
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy
- Latvia
- Liechtenstein
- Lithuania
- Luxembourg
- Malta

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:	

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 Africa:		
In North America:		
In South America:		
In Oceania:		
Total planned number of subjects/samples:	0	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 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: Belgium	
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
- ☐ 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.

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:

- Class A
- Class B
- Class C
- Class D

Classification rule:

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 manageme
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 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:

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:		
Address	Street name:	Street number:
	Postal code:	City:
	Country: Turkmenistan	
Email:		

Ethics commitee 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?

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:	

Performance study supporting documents

Appendix of documents to attach

Version 1.0

Document	Version/Date [DD-MM-YY] At time of NCA application	Version / Date [DD-MM-YY] At time of NCA authorisation / refusal	Summary of changes made	Amended as a result of NCA / REC assessment
Mandatory				
Cover letter				☐
Application form				
Investigator's Brochure (including any annexes - if applicable).[1] Non-exhaustive items: • List of General Safety and Performance Requirements that apply to the device and the methods used to demonstrate conformity with each applicable GSPR • Risk management documentation • Scientific validity documentation • Analytical performance documentation				☐
				☐
				☐
				☐
				☐
Performance study plan				☐
Performance evaluation plan				☐
Performance study synopsis				☐

[1] **See chapter I of annex XIV from EU 2017/746 for the content of investigator brochure**

A signed conformity statement according to Annex XIV, Chapter 1.4.1				☐
Example of labels				☐
Description of clinical data management including general data protection procedures.				☐

As applicable				
Test reports				☐
Proof of study performance Insurance				☐
Suitability of investigational sites and investigation site team				☐
Manufacturer's Instructions for Use (draft or final)				☐
Suitability of the investigators				☐
Recruitment procedures and advertising materials				☐
Documents to obtain informed consent, informed consent procedure, all written information to participants, payments and compensation of participants				☐
Notified Body Certificates				☐
Decisions from other countries				☐
PMPF plan				☐
Expert panel opinion				☐
National ethics committee opinion				☐
Other documents				☐

Notes

This template has been prepared by the Clinical Investigation and Evaluation Working Group of the European Commission to support document traceability in the absence of EUDAMED.

This template should be used in conjunction with the document 'Performance study – application form under *In Vitro* Medical Device Regulation'. The use of this template is not mandatory, and it is advisable to check with the relevant NCA regarding expectations for the use and completion of the template.

Fields marked as 'mandatory' are required to support a submission with respect to Regulation 2017/746, 'optional' fields may or may not be required, depending on the performance study.

With respect to the 'summary of changes made' please include a short description of the sections amended and the type of change.

Acronyms

NCA	National Competent Authority
REC	Research ethics committee
PMPF	Post-market performance follow-up

Invoice information

Danish Medicines Agency's fee for application assessment

Danish Medicines Agency's fee for assessment of applications of performance studies of in vitro diagnostic medical devices can be found on the Danish Medicines Agency's website.

Performance study plan title:	
Company	
Contact person	
Company invoice ref. number	
Address	
Phone number	
E-mail	
CVR / VAT number and EAN number	CVR / VAT number EAN number for Danish invoice recipients, if any

Danish Medicines Agency's annual inspection fee (performance studies for which authorisation is granted)

Only fill in if different from above.
Danish Medicines Agency's fee for annual inspections of performance studies of in vitro diagnostic medical devices can be found on the Danish Medicines Agency's website.

Performance study plan title:	
Company	

Contact person	
Company invoice ref. number	
Address	
Phone number	
E-mail	
CVR / VAT number and EAN number	CVR / VAT number EAN number for Danish invoice recipients, if any

Ørestads Boulevard 5
Bygning 37K, st.
2300 København S

M: dketik@dketik.dk
W: www.dvmk.dk

Medical Research Ethics Committees' fee for application assessment

Medical Research Ethics Committees' fee for assessment of applications of performance studies of in vitro diagnostic medical devices can be found on the Medical Research Ethics Committees' website.

Performance study title:
Sponsor name:
Name of the coordinating investigator (alternatively please provide the name of principal investigator):

Billing information / Information about the sponsor	
EAN number (obligatory for public authorities in Denmark):	
Contact person:	*Phone number:*
E-mail address for invoice:	*VAT number:*
Company name, address, postal code, city and country:	

Please provide the EU trial number if the application is submitted in parallel with an application for a clinical trial on medicinal products:	
Comments (for example PO number):	
Email address for receipt:	*Date:*

Invoices are issued by Danish National Center for Ethics (item number: 600).