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.

Performance study – Substantial modification of performance study under In Vitro Medical Device Regulation.

Notification form Version 1.0

Section 1. Identification of the performance study

Please provide the performance study ID (CIV-ID)	
Does this substantial modification relate to a performance study that is currently suspended/stopped?	◯ Yes ◉ No

How many patients have been recruited in the performance study

Worldwide

Europe

In the Member State you are submitting this substantial modification

Select the Member State where this performance study is ongoing:

- Austria
- Belgium
- Bulgaria
- Croatia
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy

Section 2. Subject of the substantial modification

Please provide a short rationale of this substantial modification	

Is this substantial modification likely to have an impact on subjects participating in the performance study? (Select all that apply)

- ☐ Rights of subjects
- ☐ Safety of subjects
- ☐ Health of subjects
- ☐ Other
- ☐ No impact on the subjects

Do you consider this substantial modification will likely have an impact on generated clinical data? (Select all that apply)

- ☐ Robustness of clinical performance data generated by the performance study
- ☐ Reliability of clinical performance data generated by the performance study
- ☐ Other
- ☐ No impact on clinical data

Please use the template named “appendix of documents to attach” to identify clearly which documents are being proposed for modification with this substantial modification.

I hereby certify that the information and documentation submitted with this substantial modification is correct in detail and all the information requested has been supplied.
The device for performance complies with the applicable general safety and performance requirements, apart from those covered by the performance 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 performance study information collected for this notification, has been done in compliance with the European data protection legislation (GDPR).

Date	

Name	
Position	

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Invoice information – substantial modifications

Danish Medicines Agency's fee for substantial modifications application assessment

Danish Medicines Agency's fee for assessment of applications of substantial modifications of performance studies 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 substantial modifications application assessment

Medical Research Ethics Committees' fee for assessment of applications of substantial modifications of performance studies 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 the 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: 500).