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
- Latvia
- Liechtenstein

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 in 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	