# Clinical investigation – Substantial modification of clinical investigation under Medical Device Regulation.

**Notification form** Version 1.1

## Section 1. Identification of the clinical investigation

| | |
|---|---|
| Please provide the clinical investigation ID (CIV-ID) | |
| Does this substantial modification relate to a clinical investigation that is currently suspended/stopped? | ◯ Yes<br>◯ No |

How many patients have been recruited in the clinical investigation

Worldwide

Europe

In the Member State you are submitting this substantial modification

Select the Member State where this clinical investigation is ongoing:

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

## 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 clinical investigation? (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 data generated by the investigation
- ☐ Reliability of clinical data generated by the investigation
- ☐ Other
- ☐ No impact on clinical data

Please use the template in MDCG 2021-8 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 investigated (medical) device complies with the applicable general safety and performance requirements, apart from those covered by the investigation and that every precaution has been taken to protect the health and safety of the patient and/or user.
I confirm that all the clinical investigations information collected for this notification, has been done in compliance with the European data protection legislation (GDPR).

| | |
|---|---|
| | |
| Date | |

| | |
|---|---|
| Name | |
| Position | |