**Statement of Conformity with General Safety and Performance Requirements (GSPR)**

**Investigational Medical Device**

Declaration by the manufacturer regarding conformity to GSPR for investigational medical devices.

Manufacturer:

Medical device under investigation:

Clinical Investigation Plan title:

Clinical investigation reference no. / ID no (f.eks CIP ID):

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The manufacturer of the above investigational device hereby confirms that the device in question conforms to the General Safety and Performance Requirements (GSPR) in Annex I of the Medical Device Regulation (EU) 2017/745 apart from the aspects covered by the clinical investigation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject. *This includes, where appropriate, technical and biological safety testing and pre-clinical evaluation, as well as provisions in the field of occupational safety and accident prevention, taking into consideration the state of the art.*

Date:

Signature:

Name:

Title\*:

\* The statement must be dated and signed by the managing director or regulatory affairs manager or manager responsible for compliance with the general safety and performance requirements.