**Manufacturers Statement of Compliance for investigational device**

Manufacturer:

Medical device under investigation:

Clinical investigation plan title:

Clinical investigation reference no. / ID no.:

The manufacturer of the above investigational device(s) hereby confirms that the investigational device(s) in question conform(s) to the applicable general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, 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 subjects. 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 (Representative from manufacturer’s management)