

**Statement of clinical investigation with active implantable  
medical devices**

(template)

Name of Manufacturer or Authorised EU Representative:

Address or Head-office:

States:

- That the devices it manufactures (refer which):

fulfil the relevant essential requirements of Annex 1 of the Directive 90/385/EEC, and Annex X of Decree-law no.145/2009 of 17 June, as amended, excepting the aspects, which are subject to investigation, for which, however, all necessary precautions have been taken in safeguarding the health and safety of patients and users of the medical device.

- That it shall carry out the clinical trials in conformity with the Helsinki Declaration, adopted at the 18th World Medical Assembly in Helsinki (last version).
- That it shall carry out all clinical investigation in compliance with a suitable investigation plan, corresponding to the relevant state-of-the-art in science and technique. Such a plan shall confirm or refute the Manufacturer's statements regarding the medical device and it shall include the necessary observations guaranteeing that the conclusions are scientifically valid.
- That in the trials it shall use procedures suitable for the device investigation.
- That it shall carry out the investigations in circumstances equivalent to those in which the devices are normally used.
- That the trials shall be carried out in a suitable environment under the responsibility of a physician or of a qualified and authorised technician.

- That the trials shall be carried out under informed consent of all subjects.
- That the trials shall be carried out under an insurance coverage in case of injury.

And accepts:

- To register and to report immediately to INFARMED, I.P. and all competent authorities of the Member States in which the clinical investigation is being performed, all occurring events:
  - Defects, damage and deterioration of the device features or functioning
  - Unclear labels or use instructions, which may be or have been the cause of death or of serious deterioration in the patient's or user's health
- To provide to the supervising bodies the written report, which shall include an assessment of all data collected throughout the investigation, signed by the Physician or Authorised Technician.
- To keep for a minimum period of 15 years all relevant information regarding the medical device, including this Statement, for inspection purposes.

Date: \_\_\_\_\_

Signature (Manufacturer or Authorised Representative)

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Sending this Statement to INFARMED, I.P. is highly recommended.