

Statement of medical devices / implantable active medical devices for interventional pre-market clinical studies

(template)

Name of manufacturer:

Address/ Head-office:

States:

- That the medical devices / implantable active medical devices under investigation (refer which):

fulfil the relevant essential requirements of Annex I of the Directive 93/42/EEC / Directive 90/385/EEC , as amended, and Decree-Law No. 145/2009 of June 17, except for the aspects which are being subject to investigation, for which, however, all necessary precautions have been taken in safeguarding the health and safety of patients as well as of users of the medical device;

- That he shall carry out the clinical trials in conformity with the Helsinki Declaration, adopted at the 18th World Medical Assembly in Helsinki (last version);

- That the study will be carried out under the ethical standards that promote and ensure respect for all human subjects and protect their health and rights and assuring that the goal of generating new knowledge will never take precedence over the rights and interests of individual research subjects;

- That every precaution will be taken to protect the privacy of research subjects and the confidentiality of their personal information as well as to minimise eventual damage to research subjects' personality rights as well as physical and mental integrity;

- That the study will be designed, carried out, registered and notified and its results will be reviewed and divulged in accordance with the principles of good clinical practices applicable to the sector, namely, the European Standard EN ISO 14155 and in accordance with the established in the Portuguese Law nr. 21/2014, of 16 of April;

- That he shall carry out the clinical study in compliance with a suitable protocol, corresponding to the relevant state-of-the-art in science and technique. Such a protocol 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 the clinical study shall use procedures suitable for the device investigation;
- That he shall carry out the clinical study in circumstances equivalent to those in which the devices are normally used;
- That the clinical study shall be carried out in a suitable environment under the responsibility of a physician or of a qualified and authorised technician, who will fulfil all the requirements stated on regulation and law;
- That an active monitoring system of the clinical study will be established and maintained;
- That the clinical study shall be carried out under informed consent of all subjects;
- That the clinical study shall be carried out under an insurance coverage in case of injury.

And accepts:

- To register and to report to INFARMED, I.P. and all competent authorities of the Member States in which the clinical study is being performed, all occurring serious adverse events, in accordance with article 22^o of Law No. 21/2014, April 16;
- 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 5 years or, regarding the implantable medical devices, 15 years, all relevant information regarding the medical device, including this Statement, for inspection purposes.

Date: __/__/__

Signature (sponsor)