

## ANNEX X

## CLINICAL EVALUATION

## 1. General provisions

- 1.1. As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of Annex I under the normal conditions of use of the device and the evaluation of the undesirable side-effects must be based on clinical data in particular in the case of implantable devices and devices in Class III. Taking account of any relevant harmonized standards, where appropriate, the adequacy of the clinical data must be based on:
  - 1.1.1. either a compilation of the relevant scientific literature currently available on the intended purpose of the device and the techniques employed as well as, if appropriate, a written report containing a critical evaluation of this compilation;
  - 1.1.2. or the results of all the clinical investigations made, including those carried out in conformity with Section 2.
- 1.2. All the data must remain confidential, in accordance with the provisions of Article 20.

## 2. Clinical investigations

## 2.1. Objectives

The objectives of clinical investigation are:

- to verify that, under normal conditions of use, the performance of the devices conform to those referred to in Section 3 of Annex I, and
- to determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device.

## 2.2. Ethical considerations

Clinical investigations must be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the 41st World Medical Assembly in Hong Kong in 1989. It is mandatory that all measures relating to the protection of human subjects are carried out in the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.

## 2.3. Methods

- 2.3.1. Clinical investigations must be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims for the device; these investigations must include an adequate number of observations to guarantee the scientific validity of the conclusions.
- 2.3.2. The procedures used to perform the investigations must be appropriate to the device under examination.
- 2.3.3. Clinical investigations must be performed in circumstances similar to the normal conditions of use of the device.
- 2.3.4. All the appropriate features, including those involving the safety and performances of the device, and its effect on patients must be examined.
- 2.3.5. All adverse incidents such as those specified in Article 10 must be fully recorded and notified to the competent authority.
- 2.3.6. The investigations must be performed under the responsibility of a medical practitioner or another authorized qualified person in an appropriate environment.

The medical practitioner or other authorized person must have access to the technical and clinical data regarding the device.
- 2.3.7. The written report, signed by the medical practitioner or other authorized person responsible, must contain a critical evaluation of all the data collected during the clinical investigation.