

ANNEX 6

STATEMENT CONCERNING DEVICES INTENDED FOR SPECIAL PURPOSES

3. 3.2.

For devices intended for clinical investigations, the documentation shall also contain:

- [F¹a general description of the product and its intended use,]
- design drawings, manufacturing methods, in particular as regards sterilization, and diagrams of parts, sub-assemblies, circuits, etc.,
- the descriptions and explanations necessary for the understanding of the said drawings and diagrams and of the operation of the product,
- [F¹the results of the risk analysis and a list of the standards] laid down in Article 5, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements of the Directive where the standards in Article 5 have not been applied,
- [F²if the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 10 of Annex 1, the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance, or human blood derivative, taking account of the intended purpose of the device,]
- the results of the design calculations, checks and technical tests carried out, etc.

Textual Amendments

- F1** Substituted by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (Text with EEA relevance).
- F2** Inserted by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (Text with EEA relevance).

The manufacturer shall take all necessary measures to see that the manufacturing process ensures that the products manufactured conform to the documentation referred to in 3.1 and in the first paragraph of this section.

The manufacturer may authorize the evaluation, by audit where necessary, of the effectiveness of these measures.