ANNEX 3

EC TYPE-EXAMINATION

3. The documentation must make it possible to understand the design, the manufacture and the performances of the product. The documentation shall contain the following items in particular:

— **[**[F1]a general description of the type, including any variants planned, and its intended use(s),**]**

— design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of parts, sub-assemblies, circuits, etc.,

— the descriptions and explanations necessary for the understanding of the abovementioned drawings and diagrams and of the operation of the product,

— a list of the standards referred to in Article 5, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements where the standards referred to in Article 5 have not been applied,

— **[**[F1]the results of design calculations, risk analysis, investigations and technical tests carried out, etc.,

— a declaration stating whether or not the device incorporates, as an integral part, a substance or a human blood derivative as referred to in Section 10 of Annex 1 and the data on the tests conducted in this connection 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 pre-clinical evaluation,

— the clinical evaluation referred to in Annex 7,

— the draft instruction leaflet.**]**

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).