Status: *EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.*

ANNEX VII

EC DECLARATION OF CONFORMITY

3. The technical documentation must allow assessment of the conformity of the product with the requirements of the Directive. It must include in particular:

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

— design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc.,

— the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operations of the product,

— the results of the risk analysis and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 have not been applied in full,

— **[**[F1]in the case of products placed on the market in a sterile condition, description of the methods used and the validation report,**]**

— the results of the design calculations and of the inspections carried out, etc.; if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer,

— **[**[F1]the solutions adopted as referred to in Annex I, Chapter I, Section 2,

— the pre-clinical evaluation,**]**

— **[**[F2]the clinical evaluation in accordance with Annex X,**]**

— the label and instructions for use.

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).