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

[F1 1. The EC declaration of conformity is the procedure whereby the manufacturer or his authorised representative who fulfils the obligations imposed by Section 2 and, in the case of products placed on the market in a sterile condition and devices with a measuring function, the obligations imposed by Section 5 ensures and declares that the products concerned meet the provisions of this Directive which apply to them.

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).

2. The manufacturer must prepare the technical documentation described in Section 3. The manufacturer or his authorised representative must make this documentation, including the declaration of conformity, available to the national authorities for inspection purposes for a period ending at least five years after the last product has been manufactured. In the case of implantable devices the period shall be at least 15 years after the last product has been manufactured.]

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.

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.*

Textual Amendments

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).

[[F1]4. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. He shall notify the competent authorities of the following incidents immediately on learning of them:**]**

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(ii) any technical or medical reason connected with the characteristics on the performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

5. With products placed on the market in sterile condition and Class I devices with a measuring function, the manufacturer must observe not only the provisions laid down in this Annex but also one of the procedures referred to in **[**[F1]Annex II, IV, V or VI**]**. Application of the abovementioned Annexes and the intervention by the notified body is limited to:

— in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions,

— in the case of devices with a measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Section 6.1. of this Annex is applicable.

6. Application to devices in Class IIa

In line with Article 11 (2), this Annex may apply to products in Class IIa, subject to the following derogation:

6.1. where this Annex is applied in conjunction with the procedure referred to in Annex IV, V or VI, the declaration of conformity referred to in the abovementioned Annexes forms a single declaration. As regards the declaration based on this Annex, the manufacturer must ensure and declare that the product design meets the provisions of this Directive which apply to it.