

ANNEX VII

EC DECLARATION OF CONFORMITY

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:

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 \(Text with EEA relevance\).](#)

- 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.