

ANNEX VI

EC DECLARATION OF CONFORMITY (Product quality assurance)

5. Administrative provisions

- 5.1. [^{F1}The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities:]

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

- the declaration of conformity,
- the documentation referred to in the seventh indent of Section 3.1,
- the changes referred to in Section 3.4,
- the decisions and reports from the notified body as referred to in the final indent of Section 3.4 and in Sections 4.3 and 4.4,
- where appropriate, the certificate of conformity referred to in Annex III.

- ^{F2}5.2.

Textual Amendments

- F2** Deleted by [Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.](#)