ANNEX V

EC DECLARATION OF CONFORMITY
(Production 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 fourth indent of Section 3.1,
— the changes referred to in Section 3.4,
— the documentation referred to in the seventh indent of Section 3.1,
— the decisions and reports from the notified body as referred to in Sections 4.3 and 4.4,
— where appropriate, the type-examination certificate 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.