

ANNEX 2

EC DECLARATION OF CONFORMITY (Complete quality assurance system)

- [^{F1}6. Administrative provisions
- [^{F2}6.1. For at least 15 years from the last date of manufacture of the product, the manufacturer or his authorised representative shall keep available for the national authorities:
- the declaration of conformity,
 - the documentation referred to in the second indent of Section 3.1, and in particular the documentation, data and records referred to in the second paragraph of Section 3.2,
 - the amendments referred to in Section 3.4,
 - the documentation referred to in Section 4.2,
 - the decisions and reports of the notified body referred to in Sections 3.4, 4.3, 5.3 and 5.4.]]

Textual Amendments

- F2** 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).

Textual Amendments

- F1** Substituted by [Council Directive 93/68/EEC](#) of 22 July 1993 amending [Directives 87/404/EEC](#) (simple pressure vessels), [88/378/EEC](#) (safety of toys), [89/106/EEC](#) (construction products), [89/336/EEC](#) (electromagnetic compatibility), [89/392/EEC](#) (machinery), [89/686/EEC](#) (personal protective equipment), [90/384/EEC](#) (non-automatic weighing instruments), [90/385/EEC](#) (active implantable medicinal devices), [90/396/EEC](#) (appliances burning gaseous fuels), [91/263/EEC](#) (telecommunications terminal equipment), [92/42/EEC](#) (new hot-water boilers fired with liquid or gaseous fuels) and [73/23/EEC](#) (electrical equipment designed for use within certain voltage limits).