

ANNEX IV

EC VERIFICATION

7. Administrative provisions

[^{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 Section 2,
- the certificates referred to in Sections 5.2 and 6.4,
- where appropriate, the type-examination certificate referred to in Annex III.