ANNEX 1

ESSENTIAL REQUIREMENTS

I.GENERAL REQUIREMENTS

[F1 5a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex 7.**]**

Textual Amendments

F1 Inserted 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).