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## ANNEX 1

## ESSENTIAL REQUIREMENTS

## I.GENERAL REQUIREMENTS

[F15a. 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).