

ANNEX IV

EC VERIFICATION

6. Statistical verification

- [^{F1}6.3. Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the harmonised standards referred to in Article 5, taking account of the specific nature of the product categories in question.]

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).