ANNEX 1

ESSENTIAL REQUIREMENTS

II.REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

9. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in I. 'General requirements', with particular attention being paid to:

— the choice of materials used, particularly as regards toxicity aspects,

— mutual compatibility between the materials used and biological tissues, cells and body fluids, account being taken of the anticipated use of the device,

— compatibility of the devices with the substances they are intended to administer,

— the quality of the connections, particularly in respect of safety,

— the reliability of the source of energy,

— if appropriate, that they are leakproof,

— proper functioning of the programming and control systems, including software.**[**[F1] For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.**]**

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).