# ANNEX 1 U.K.

## ESSENTIAL REQUIREMENTS

## I.GENERAL REQUIREMENTS

1. The devices must be designed and manufactured in such a way that, when implanted under the conditions and for the purposes laid down, their use does not compromise the clinical condition or the safety of patients. They must not present any risk to the persons implanting them or, where applicable, to other persons.

2. The devices must achieve the performances intended by the manufacturer, viz. be designed and manufactured in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a) as specified by him.

3. The characteristics and performances referred to in sections 1 and 2 must not be adversely affected to such a degree that the clinical condition and safety of the patients or, as appropriate, of other persons are compromised during the lifetime of the device anticipated by the manufacturer, where the device is subjected to stresses which may occur during normal conditions of use.

4. The devices must be designed, manufactured and packed in such a way that their characteristics and performances are not adversely affected in the storage and transport conditions laid down by the manufacturer (temperature, humidity, etc.).

5. Any side effects or undesirable conditions must constitute acceptable risks when weighed against the performances intended.

**[**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).

## II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION U.K.

6. The solutions adopted by the manufacturer for the design and construction of the devices must comply with safety principles taking account of the generally acknowledged state of the art.

7. Implantable devices must be designed, manufactured and packed in a non-reusable pack according to appropriate procedures to ensure they are sterile when placed on the market and, in the storage and transport conditions stipulated by the manufacturer, remain so until the packaging is removed and they are implanted.

8. Devices must be designed and manufactured in such a way as to remove or minimize as far as possible:

— the risk of physical injury in connection with their physical, including dimensional, features,

— risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,

— risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration,
— risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment,
— **[**F2risks connected with ionising radiation from radioactive substances included in the device, in compliance with the protection requirements laid down in Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation(1)and Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure(2),**]**
— risks which may arise where maintenance and calibration are impossible, including:
  — excessive increase of leakage currents,
  — ageing of the materials used,
  — excess heat generated by the device,
  — decreased accuracy of any measuring or control mechanism.

**Textual Amendments**

**F2** 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).

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.**]**

**[**F2 10. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC, and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through

its committee in accordance with Regulation (EC) No 726/2004[(3)] on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance, including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of the incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the device.

When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance to the device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance to the device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.**]**

11. The devices and, if appropriate, their component parts must be identified to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices and their component parts.

12. Devices must bear a code by which they and their manufacturer can be unequivocably identified (particularly with regard to the type of device and year of manufacture); it must be possible to read this code, if necessary, without the need for a surgical operation.

13. When a device or its accessories bear instructions required for the operation of the device or indicate operating or adjustment parameters, by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

14. Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:

14.1. On the sterile pack:

— the method of sterilization,

— an indication permitting this packaging to be recognized as such,

— the name and address of the manufacturer,

— a description of the device,

— if the device is intended for clinical investigations, the words: ‘exclusively for clinical investigations’,

— if the device is custom-made, the words ‘custom-made device’,
— a declaration that the implantable device is in a sterile condition,
— the month and year of manufacture,
— an indication of the time limit for implanting a device safely.

14.2. On the sales packaging:
— **[**[F2]the name and address of the manufacturer and the name and address of the authorised representative, where the manufacturer does not have a registered place of business in the Community,**]**
— a description of the device,
— the purpose of the device,
— the relevant characteristics for its use,
— if the device is intended for clinical investigations, the words: ‘exclusively for clinical investigations’,
— if the device is custom-made, the words: ‘custom-made device’,
— a declaration that the implantable device is in a sterile condition,
— the month and year of manufacture,
— an indication of the time limit for implanting a device safely,
— the conditions for transporting and staring the device**[**[F2],**]**
— **[**[F1]in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.**]**

15. When placed on the market, each device must be accompanied by instructions for use giving the following particulars:
— the year of authorization to affix the CE mark,
— the details referred to in 14,1 and 14.2, with the exception of those referred to in the eighth and ninth indents,
— the performances referred to in section 2 and any undesirable side effects,
— information allowing the physician to select a suitable device and the corresponding software and accessories,
— information constituting the instructions for use allowing the physician and, where appropriate, the patient to use the device, its accessories and software correctly, as well as information on the nature, scope and times for operating controls and trials and, where appropriate, maintenance measures,
— information allowing, if appropriate, certain risks in connection with implantation of the device to be avoided,
— information regarding the risks of reciprocal interference[(4)] in connection with the presence of the device during specific investigations or treatment,
— the necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of resterilization,
— an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the essential requirements.

The instruction leaflet must also include details allowing the physician to brief the patient on the contra-indications and the precautions to be taken. These details should cover in particular:
— information allowing the lifetime of the energy source to be established,
— precautions to be taken should changes occur in the device's performance,

— precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, etc.,

— adequate information regarding the medicinal products which the device in question is designed to administer**[**F2**,]**

— **[**F1date of issue or the latest revision of the instructions for use.**]**

16. Confirmation that the device satisfies the requirements in respect of characteristics and performances, as referred to in I. ‘General requirements’, in normal conditions of use, and the evaluation of the side effects or undesirable effects must be based on clinical data established in accordance with Annex 7.

**(1)** **[**[F2]OJ L 159, 29.6.1996, p. 1.**]**

**(2)** **[**[F2]OJ L 180, 9.7.1997, p. 22.**]**

**(3)** **[**[F2]Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1). Regulation as last amended by Regulation (EC) No 1901/2006.**]**

**(4)** 'Risks of reciprocal interference' means adverse effects on the device caused by instruments present at the time of investigations or treatment, and vice versa.

**Textual Amendments**

**F2** 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).