

## ANNEX I

## ESSENTIAL REQUIREMENTS

## II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

## 13. Information supplied by the manufacturer

- [<sup>F1</sup>13.1. Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.]

This information comprises the details on the label and the data in the instructions for use.

As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.

Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.

**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 \(Text with EEA relevance\).](#)

- 13.2. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.

- 13.3. *The label* must bear the following particulars:

- (a) [<sup>F1</sup>the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community;]
- (b) [<sup>F1</sup>the details strictly necessary to identify the device and the contents of the packaging especially for the users;]
- (c) where appropriate, the word ‘STERILE’;
- (d) where appropriate, the batch code, preceded by the word ‘LOT’, or the serial number;
- (e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;
- (f) [<sup>F1</sup>where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;]
- (g) if the device is custom-made, the words ‘custom-made device’;

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*Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.*

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- (h) if the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’;
- (i) any special storage and/or handling conditions;
- (j) any special operating instructions;
- (k) any warnings and/or precautions to take;
- (l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;
- (m) where applicable, method of sterilization<sup>[F2];</sup>
- (n) <sup>[F3</sup>in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.]

#### **Textual Amendments**

- F2** Substituted by [Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma.](#)
- F3** Inserted by [Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma.](#)

- 13.4. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.
- 13.5. Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.
- 13.6. Where appropriate, the instructions for use must contain the following particulars:
  - (a) the details referred to in Section 13.3, with the exception of (d) and (e);
  - (b) the performances referred to in Section 3 and any undesirable side-effects;
  - (c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;
  - (d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;
  - (e) where appropriate, information to avoid certain risks in connection with implantation of the device;
  - (f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;
  - (g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilization;

- (h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of reuses.

Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I<sup>[F1]</sup>.

[<sup>F4</sup>If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;]

- (i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);
- (j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.

#### Textual Amendments

- F4** 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 \(Text with EEA relevance\).](#)

The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:

- (k) precautions to be taken in the event of changes in the performance of the device;
- (l) 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, thermal ignition sources, etc.;
- (m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;
- (n) precautions to be taken against any special, unusual risks related to the disposal of the device;
- (o) [<sup>F1</sup>medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;]
- (p) degree of accuracy claimed for devices with a measuring function<sup>[F1]</sup>;
- (q) [<sup>F4</sup>date of issue or the latest revision of the instructions for use.]