

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Article 12

[^{F1}Particular procedure for systems and procedure packs and procedure for sterilisation]

1 By way of derogation from Article 11 this Article shall apply to systems and procedure packs.

2 Any natural or legal person who puts devices bearing the CE marking together within their intended purpose and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack, shall draw up a declaration by which he states that:

- a he has verified the, mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions; and
- b he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
- c the whole activity is subjected to appropriate methods of internal control and inspection.

Where the conditions above are not met, as in cases where the system or procedure pack incorporate devices which do not bear a CE marking or where the chosen combination of devices is not compatible in view of their original intended use, the system or procedure pack shall be treated as a device in its own right and as such be subjected to the relevant procedure pursuant to Article 11.

[^{F13} Any natural or legal person who sterilises, for the purpose of placing on the market, systems or procedure packs referred to in paragraph 2 or other CE-marked medical devices designed by their manufacturers to be sterilised before use, shall, at his choice, follow one of the procedures referred to in Annex II or V. The application of the abovementioned Annexes and the intervention of the notified body are limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged. The person shall draw up a declaration stating that sterilisation has been carried out in accordance with the manufacturer's instructions.]

4 The products referred to in paragraphs 2 and 3 themselves shall not bear an additional CE marking. They shall be accompanied by the information referred to in point 13 of Annex I which includes, where appropriate, the information supplied by the manufacturers of the devices which have been put together. [^{F1}The declarations referred to in paragraphs 2 and 3 shall be kept at the disposal of the competent authorities for a period of five years.]

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