

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

Article 11

Conformity assessment procedures

1 In the case of devices falling within Class III, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either:

- a follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); or
- b follow the procedure relating to the EC type-examination set out in Annex III, coupled with:
 - (i) the procedure relating to the EC verification set out in Annex IV;
or
 - (ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance).

2 In the case of devices falling within Class IIa, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure relating to the EC declaration of conformity set out in Annex VII, coupled with either:

- a the procedure relating to the EC verification set out in Annex IV;
or
- b the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance);
or
- c the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance).

Instead of applying these procedures, the manufacturer may also follow the procedure referred to in paragraph 3 (a).

3 In the case of devices falling within Class IIb, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either:

- a follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); in this case, point 4 of Annex II is not applicable; or
- b follow the procedure relating to the EC type-examination set out in Annex III, coupled with:
 - (i) the procedure relating to the EC verification set out in Annex IV;
or
 - (ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance);

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or

- (iii) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance).

4 The Commission shall, no later than five years from the date of implementation of this Directive, submit a report to the Council on the operation of the provisions referred to in Article 10 (1), Article 15 (1), in particular in respect of Class I and Class IIa devices, and on the operation of the provisions referred to in Annex II, Section 4.3 second and third subparagraphs and in Annex III, Section 5 second and third subparagraphs to this Directive, accompanied, if necessary, by appropriate proposals.

5 In the case of devices falling within Class I, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex VII and draw up the EC declaration of conformity required before placing the device on the market.

6 In the case of custom-made devices, the manufacturer shall follow the procedure referred to in Annex VIII and draw up the statement set out in that Annex before placing each device on the market.

Member States may require that the manufacturer shall submit to the competent authority a list of such devices which have been put into service in their territory.

7 During the conformity assessment procedure for a device, the manufacturer and/or the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with this Directive at an intermediate stage of manufacture.

8 The manufacturer may instruct his authorized representative^[F1] established in the Community] to initiate the procedures provided for in Annexes III, IV, VII and VIII.

9 Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer, or his authorized representative^[F1] established in the Community], may apply to a body of his choice within the framework of the tasks for which the body has been notified.

10 The notified body may require, where duly justified, any information or data, which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

11 Decisions taken by the notified bodies in accordance with ^[F2]Annexes II, III, V and VI] shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, ^[F2]for further periods of a maximum length of five years].

12 The records and correspondence relating to the procedures referred to in paragraphs 1 to 6 shall be in an official language of the Member State in which the procedures are carried out and/or in another Community language acceptable to the notified body.

13 By derogation from paragraphs 1 to 6, the competent authorities may authorize, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 to 6 have not been carried out and the use of which is in the interest of protection of health.

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[^{F3}14 The measures designed to amend non-essential elements of this Directive, by supplementing it, relating to the means by which, in the light of technical progress and considering the intended users of the devices concerned, the information laid down in Annex I Section 13.1 may be set out, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).]

Textual Amendments

- F1** Deleted 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).
- 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).
- F3** 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).