

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

Article 16

Notified bodies

1 The Member States shall notify the Commission and other Member States of the bodies which they have designated for carrying out the tasks pertaining to the procedures referred to in Article 11 and the specific tasks for which the bodies have been designated. The Commission shall assign identification numbers to these bodies, hereinafter referred to as 'notified bodies'.

The Commission shall publish a list of the notified bodies, together with the identification numbers it has allocated to them and the tasks for which they have been notified, in the *Official Journal of the European Communities*. It shall ensure that the list is kept up to date.

2 Member States shall apply the criteria set out in Annex XI for the designation of bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonized standards shall be presumed to meet the relevant criteria.

[^{F1}When appropriate in the light of technical progress, the detailed measures necessary to ensure a consistent application of the criteria set out in Annex XI for the designation of bodies by the Member States shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).]

3 A Member State that has notified a body shall withdraw that notification if it finds that the body no longer meets the criteria referred to in paragraph 2. It shall immediately inform the other Member States and the Commission thereof.

4 The notified body and the manufacturer, or his authorized representative [^{F2} established in the Community], shall lay down, by common accord, the time limits for completion of the assessment and verification operations referred to in Annexes II to VI.

[^{F3}^{F4}⁵ The notified body shall inform its competent authority about all certificates issued, modified, supplemented, suspended, withdrawn or refused and the other notified bodies within the scope of this Directive about certificates suspended, withdrawn or refused and, on request, about certificates issued. The notified body shall also make available, on request, all additional relevant information.]

6 Where a notified body finds that pertinent requirements of this Directive have not been met or are no longer met by the manufacturer or where a certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. In the case of suspension or withdrawal of the certificate or of any restriction placed on it or in cases where an intervention of the competent authority may become necessary, the notified body shall inform its competent authority thereof. The Member State shall inform the other Member States and the Commission.

7 The notified body shall, on request, supply all relevant information and documents including budgetary documents, required to enable the Member State to verify compliance with Annex XI requirements.]

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.

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).
- F2** 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).
- F3** Inserted by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- F4** 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).