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

[F1 Article 13

Decisions with regard to classification and derogation clause

1 A Member State shall submit a duly substantiated request to the Commission and ask it to take the necessary measures in the following situations:

a that Member State considers that the application of the classification rules set out in Annex IX requires a decision with regard to the classification of a given device or category of devices;

b that Member State considers that a given device or family of devices should, by way of derogation from the provisions of Annex IX, be classified in another class;

c that Member State considers that the conformity of a device or family of devices should, by way of derogation from Article 11, be established by applying solely one of the given procedures chosen from among those referred to in Article 11;

d that Member State considers that a decision is required as to whether a particular product or product group falls within one of the definitions in Article 1(2)(a) to (e).

The measures referred to in the first subparagraph of this paragraph shall, as appropriate, be adopted in accordance with the procedure referred to in Article 7(2).

2 The Commission shall inform the Member States of the measures taken.**]**

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).