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

Article 22

Implementation, transitional provisions

1 Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1994. They shall immediately inform the Commission thereof.

The Standing Committee referred to in Article 7 may assume its tasks from the date of notification(1) of this Directive. The Member States may take the measures referred to in Article 16 on notification of this Directive.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such a reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Member States shall apply these provisions with effect from 1 January 1995.

2 Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

3 Member States shall take the necessary action to ensure that the notified bodies which are responsible pursuant to Article 11 (1) to (5) for conformity assessment take account of any relevant information regarding the characteristics and performance of such devices, including in particular the results of any relevant tests and verification already carried out under pre-existing national law, regulations or administrative provisions in respect of such devices.

[[F1]4 Member States shall accept:

— devices which conform to the rules in force in their territory on 31 December 1994 being placed on the market during a period of five years following the adoption of this Directive, and

— the aforementioned devices being put into service until 30 June 2001 at the latest.**]**

In the case of devices which have been subjected to EEC pattern approval in accordance with Directive 76/764/EEC, Member States shall accept their being placed on the market and put into service during the period up to 30 June 2004.

Textual Amendments

F1 Substituted by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

(**1**) This Directive was notified to the Member States on 29 June 1993.