Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic 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 7 December 1999. They shall immediately inform the Commission thereof.

Member States shall apply these provisions with effect from 7 June 2000.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

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

3 The Committee referred to in Article 7 may undertake its tasks from the date of entry into force of this Directive. The Member States may take the measures referred to in Article 15 **[**[X1]as from the entry into force of this Directive.**]**

4 Member States shall take the necessary action to ensure that the notified bodies which are responsible pursuant to Article 9 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 test and verification already carried out under pre-existing national law, regulations or administrative provisions in respect of such devices.

5 During a period of five years following the entry into force of this Directive, Member States shall accept the placing on the market of devices which conform to the rules in force in their territory on the date on which this Directive enters into force. For an additional period of two years, the said devices may be put into service.

Editorial Information

X1 Substituted by Corrigendum to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (Official Journal of the European Communities L 331 of 7 December 1998).