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

Article 12

European databank

1 Regulatory data in accordance with this Directive shall be stored in a European databank accessible to the competent authorities to enable them to carry out their tasks relating to this Directive on a well-informed basis.

The databank shall contain the following:

a data relating to registration of manufacturers and devices in accordance with Article 10;

b data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedure as laid down in Annexes III to VII;

c data obtained in accordance with the vigilance procedure as defined in Article 11.

2 Data shall be forwarded in a standardised format.

[[F1]3 The procedures implementing this Article shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.