Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)

[F1 Article 10b

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a data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedures as laid down in Annexes 2 to 5;

b data obtained in accordance with the vigilance procedure as defined in Article 8;

c data relating to clinical investigations referred to in Article 10.

2 Data shall be forwarded in a standardised format.

3 The measures necessary for the implementation of paragraphs 1 and 2 of this Article, in particular paragraph 1(c), shall be adopted in accordance with the regulatory procedure referred to in Article 6(3).**]**

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).