

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 15

1 Without prejudice to the existing national provisions and practices on medical confidentiality, Member States shall ensure that all the Parties involved in the application of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks.

This does not affect the obligations of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

- 2 The following information shall not be treated as confidential:
- a information on the registration of persons responsible for placing devices on the market in accordance with Article 10a;
 - b information to users sent out by the manufacturer, authorised representative or distributor in relation to a measure in accordance with Article 8;
 - c information contained in certificates issued, modified, supplemented, suspended or withdrawn.

3 The measures designed to amend non-essential elements of this Directive, *inter alia* by supplementing it, relating to the determination of the conditions under which information other than that referred to in paragraph 2, and in particular concerning any obligation for manufacturers to prepare and make available a summary of the information and data related to the device, may be made publicly available shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 6(4).]

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 \(Text with EEA relevance\).](#)