# 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)

## 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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) Council Directive 93/42/EEC[(3)] requires the Commission to submit a report to the Council, no later than five years from the date of implementation of that Directive, concerning: (i) information on incidents occurring following the placing of devices on the market, (ii) clinical investigation carried out in accordance with the procedure set out in Annex VIII to Directive 93/42/EEC, and (iii) design examination and EC type examination of medical devices that incorporate, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[(4)] and which is liable to act upon the body with action ancillary to that of the device.

(2) The Commission brought forward the conclusions of that report in its Communication to the Council and the European Parliament on medical devices which, at the request of the Member States, was expanded to cover all aspects of the Community regulatory framework for medical devices.

(3) This Communication was welcomed by the Council in its Conclusions on medical devices of 2 December 2003[(5)]. It was also discussed by the European Parliament which

on 3 June 2003 adopted a resolution on the health implications of Directive 93/42/EEC[(6)].

(4) Following from the conclusions drawn in that Communication it is necessary and appropriate to amend Council Directive 90/385/EEC[(7)], Directive 93/42/EEC and Directive 98/8/EC of the European Parliament and of the Council[(8)].

(5) To ensure consistency of interpretation and implementation between Directives 93/42/EEC and 90/385/EEC the legal framework related to issues such as authorised representative, the European databank, health protection measures, and the application of Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma, as introduced by Directive 2000/70/EC[(9)], should be extended to Directive 90/385/EEC. The application of the provisions on medical devices incorporating stable derivates of human blood or human plasma includes application of Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC[(10)].

(6) It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Software for general purposes when used in a healthcare setting is not a medical device.

(7) Particular care should be taken to ensure that the reprocessing of medical devices does not endanger patients' safety or health. It is therefore necessary to provide clarification on the definition of the term 'single use', as well as to make provision for uniform labelling and instructions for use. Moreover, the Commission should engage in further analysis in order to see if additional measures are appropriate to ensure a high level of protection for patients.

(8) In the light of technical innovation and the development of initiatives at the international level it is necessary to enhance the provisions on clinical evaluation, including clarification that clinical data is generally required for all devices regardless of classification and the possibility to centralise data on clinical investigations in the European databank.

(9) In order to provide clearer evidence of the compliance of custom-made device manufacturers, an explicit requirement for a post market production review system involving incident reporting to authorities should be introduced, as is already in place for other devices, and to enhance patient information, a requirement should be introduced that the 'Statement' under Annex VIII to Directive 93/42/EEC should be available to the patient and that it should contain the name of the manufacturer.

(10) In the light of technical progress in information technology and medical devices, a process should be provided to allow information supplied by the manufacturer to be available by other means.

(11) Manufacturers of Class I sterile and/or measuring medical devices should be given the option of using the full quality assurance conformity assessment module in order to provide them with more flexibility in the choice of compliance modules.

(12) In order to support market surveillance activities by Member States it is necessary and appropriate, in the case of implantable devices, to increase the time period for the retention of documents for administrative purposes to at least 15 years.

(13) For the appropriate and efficient functioning of Directive 93/42/EEC as regards regulatory advice on classification issues arising at national level, in particular on whether or not a product falls under the definition of a medical device, it is in the interest of national market surveillance and the health and safety of humans to establish a procedure for decisions on whether or not a product falls under the medical device definition.

(14) To ensure that, where a manufacturer does not have a registered place of business in the Community, authorities have a single individual person authorised by the manufacturer whom they can address in matters relating to the compliance of the devices with the Directives it is necessary to introduce an obligation for such manufacturers to designate an authorised representative for a device. This designation should be effective at least for all devices of the same model.

(15) To further ensure public health and safety it is necessary to provide for a more consistent application of the provisions on health protection measures. Particular care should be taken to ensure that, when in use, the products do not endanger patients' health or safety.

(16) In support of transparency in Community legislation, certain information related to medical devices and their conformity with Directive 93/42/EEC, in particular information on registration, on vigilance reports and on certificates, should be available to any interested party and the general public.

(17) To better coordinate the application and efficiency of national resources when applied to issues related to Directive 93/42/EEC, the Member States should cooperate with each other and at international level.

(18) As design for patient safety initiatives play an increasing role in public health policy, it is necessary to expressly set out the need to consider ergonomic design in the essential requirements. In addition the level of training and knowledge of the user, such as in the case of a lay user, should be further emphasised within the essential requirements. The manufacturer should place particular emphasis on the consequences of misuse of the product and its adverse effects on the human body.

(19) In the light of experience gained regarding activities of both the notified bodies and the authorities in the assessment of devices which require intervention of the appropriate authorities for medicines and human blood derivatives their duties and tasks should be clarified.

(20) Taking account of the growing importance of software in the field of medical devices, be it as stand alone or as software incorporated in a device, validation of software in accordance with the state of the art should be an essential requirement.

(21) In the light of the increased use of third Parties to carry out the design and manufacture of devices on behalf of the manufacturer, it is important that the manufacturer demonstrates that he applies adequate controls to the third party to continue to ensure the efficient operating of the quality system.

(22) The classification rules are based on the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the devices. Explicit prior authorisation with regard to conformity, including an assessment of the design documentation, is required for Class III devices to be placed on the market. In performing its duties under the quality assurance and verification conformity assessment modules for all other classes of devices, it is essential and necessary for a notified body, in order to be assured of the compliance of the manufacturer with Directive 93/42/EEC, to review the design documentation for the medical device. The depth and extent of this review should be commensurate with the classification of the device, the novelty of the intended treatment, the degree of intervention, the novelty of the technology or construction materials, and the complexity of the design and/or technology. This review can be achieved by taking a representative example of design documentation of one or more type(s) of devices from those being manufactured. Further review(s), and in particular the assessment of changes to the design that could affect conformity with the essential requirements, should be part of the surveillance activities of the notified body.

(23) It is necessary to remove the incoherence in the classification rules as a result of which invasive devices with respect to body orifices intended for connection to an active Class I medical device were not classified.

(24) The measures necessary for the implementation of Directive 90/385/EEC and Directive 93/42/EEC should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(11)].

(25) In particular, power should be conferred on the Commission to adapt classification rules for medical devices, to adapt the means by which the information needed to use medical devices safely and properly may be set out, to determine conditions for making certain information publicly available, to adapt the provisions on clinical investigations set out in certain Annexes, to adopt particular requirements for placing certain medical devices on the market or putting them into service, and to take decisions to withdraw such devices from the market for reasons of protection of health or safety. Since those measures are of general scope and are designed to amend or supplement Directive 90/385/EEC and Directive 93/42/EEC by the modification or addition of non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(26) When, on imperative grounds of urgency, the normal time limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to use the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for taking decisions on withdrawal of certain medical devices from the market and for the

adoption of particular requirements for placing such devices on the market or putting them into service for reasons of protection of health or safety.

(27) The Commission should give a mandate to CEN and/or Cenelec to specify technical requirements and a suitable specific label for phthalate-containing devices within 12 months after entry into force of this Directive.

(28) Many Member States have established recommendations with the aim of reducing or limiting the use of medical devices containing critical phthalates on children, pregnant and nursing women and other patients at risk. To enable medical professionals to avoid such risks, devices which possibly release phthalates to the body of the patient should be labelled accordingly.

(29) In accordance with the essential requirements on the design and manufacture of medical devices, manufacturers should avoid the use of substances that may possibly compromise the health of patients, in particular of substances which are carcinogenic, mutagenic or toxic to reproduction, and should, as appropriate, strive to develop alternative substances or products with a lower risk potential.

(30) It should be clarified that alongside Directives 90/385/EEC and 93/42/EEC, in vitro diagnostic medical devices, which are the subject of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[(12)], should also be excluded from the scope of Directive 98/8/EC.

(31) In accordance with point 34 of the Interinstitutional agreement on better law-making[(13)], Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.

(32) Directives 90/385/EEC, 93/42/EEC and 98/8/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

(**1**) OJ C 195, 18.8.2006, p. 14.

(**2**) Opinion of the European Parliament of 29 March 2007 (not yet published in the Official Journal) and Council Decision of 23 July 2007.

(**3**) OJ L 169, 12.7.1993, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

(**4**) OJ L 311, 28.11.2001, p. 67. Directive as last amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council (OJ L 378, 27.12.2006, p. 1).

(**5**) OJ C 20, 24.1.2004, p. 1.

(**6**) OJ C 68 E, 18.3.2004, p. 85.

(**7**) OJ L 189, 20.7.1990, p. 17. Directive as last amended by Regulation (EC) No 1882/2003.

(**8**) OJ L 123, 24.4.1998, p. 1. Directive as last amended by Commission Directive 2007/20/EC (OJ L 94, 4.4.2007, p. 23).

(**9**) Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma (OJ L 313, 13.12.2000, p. 22).

(**10**) OJ L 33, 8.2.2003, p. 30.

(**11**) OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

(**12**) OJ L 331, 7.12.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.

(**13**) OJ C 321, 31.12.2003, p. 1.