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)

Article 1

Directive 90/385/EEC is hereby amended as follows:

1. Article 1 shall be amended as follows:

(a) paragraph 2 shall be amended as follows:

(i) point (a) shall be replaced by the following:

(a) "medical device" means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

(ii) points (d), (e) and (f) shall be replaced by the following:

(d) "custom-made device" means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made devices;

(e) "device intended for clinical investigation" means any device intended for use by a duly qualified medical practitioner when conducting clinical investigations as referred to in Section 2.1 of Annex 7 in an adequate human clinical environment.

For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorised to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner;

(f) "intended purpose" means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional material;

(iii) the following points shall be added:

(j) "authorised representative" means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Directive;

(k) "clinical data" means the safety and/or performance information that is generated from the use of a device. Clinical data are sourced from:

— clinical investigation(s) of the device concerned, or

— clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated, or

— published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated.;

(b) paragraph 3 shall be replaced by the following:

3. Where an active implantable medical device is intended to administer a substance defined as a medicinal product within the meaning of Article 1 of Directive 2001/83/EC[(1)], that device shall be governed by this Directive, without prejudice to the provisions of Directive 2001/83/EC with regard to the medicinal product.

(c) paragraph 4 shall be replaced by the following:

4. Where an active implantable medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC and which is liable to act upon the human body with action that is ancillary to that of the device, that device shall be evaluated and authorised in accordance with this Directive.;

(d) the following paragraph shall be inserted:

4a. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of Article 1 of Directive 2001/83/EC and which is liable to act upon the human body with action that is ancillary to that of the device, hereinafter referred to as a "human blood derivative", that device shall be assessed and authorised in accordance with this Directive.;

(e) paragraph 5 shall be replaced by the following:

5. This Directive constitutes a specific Directive within the meaning of Article 1(4) of Directive 2004/108/EC[(2)].;

(f) the following paragraph shall be added:

6. This Directive shall not apply to:

a medicinal products covered by Directive 2001/83/EC. In deciding whether a product falls under that Directive or this Directive, particular account shall be taken of the principal mode of action of the product;

b human blood, blood products, plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells with the exception of devices referred to in paragraph 4a;

c transplants or tissues or cells of human origin or to products incorporating or derived from tissues or cells of human origin, with the exception of devices referred to in paragraph 4a;

d transplants or tissues or cells of animal origin, unless a device is manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue.;

2. Article 2 shall be replaced by the following:

Article 2

Member States shall take all necessary steps to ensure that the devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied, properly implanted and/or properly installed, maintained and used in accordance with their intended purposes.;

3. Article 3 shall be replaced by the following:

Article 3

The active implantable medical devices referred to in Article 1(2)(c), (d) and (e), hereinafter referred to as "devices", shall satisfy the essential requirements set out in Annex 1 which apply to them, account being taken of the intended purpose of the devices concerned.

Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery[(3)] shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex 1 to this Directive.;

4. in Article 4, paragraphs 1, 2 and 3 shall be replaced by the following:

1. Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices complying with the provisions of this Directive and bearing the CE marking provided for in Article 12, which indicates that they have been the subject of an assessment of their conformity in accordance with Article 9.

2 Member States shall not create any obstacles to:

— devices intended for clinical investigations being made available to duly qualified medical practitioners or authorised persons for that purpose if they satisfy the conditions laid down in Article 10 and in Annex 6,

— custom-made devices being placed on the market and put into service if they satisfy the conditions laid down in Annex 6 and are accompanied by the statement, which shall be available to the particular identified patient, referred to in that Annex.

These devices shall not bear the CE marking.

3 At trade fairs, exhibitions, demonstrations, etc., Member States shall not create any obstacle to the showing of devices which do not conform to this Directive, provided that a visible sign clearly indicates that such devices do not conform and cannot be marketed or put into service until they have been made to comply by the manufacturer or his authorised representative.;

5. Article 5 shall be replaced by the following:

Article 5

1 Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards adopted pursuant to the harmonised standards the references of which have been published in the Official Journal of the European Union; Member States shall publish the references of such national standards.

2 For the purposes of this Directive, reference to harmonised standards also includes the monographs of the European Pharmacopoeia notably on interaction between medicinal products and materials used in devices containing such medicinal products, the references of which have been published in the *Official Journal of the European Union*.;

6. Article 6 shall be amended as follows:

(a) in paragraph 1 the reference ‘83/189/EEC’ shall be replaced by the reference

98/34/EC[(4)]

(b) paragraph 2 shall be replaced by the following:

2. The Commission shall be assisted by a standing committee (hereinafter referred to as the Committee).

3 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

7. Article 8 shall be replaced by the following:

Article 8

1 Member States shall take the necessary steps to ensure that information brought to their knowledge regarding the incidents mentioned below involving a device is recorded and evaluated in a centralised manner:

a any malfunction of or deterioration in the characteristics and performances of a device, as well as any inadequacy in the labelling or in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

b any technical or medical reason in relation to the characteristics or performances of a device for the reasons referred to in point (a), leading to systematic recall of devices of the same type by the manufacturer.

2 Where a Member State requires medical practitioners or the medical institutions to inform the competent authorities of any incidents referred to in paragraph 1, it shall take the necessary steps to ensure that the manufacturer of the device concerned, or his authorised representative, is also informed of the incident.

3 After carrying out an assessment, if possible together with the manufacturer or his authorised representative, Member States shall, without prejudice to Article 7, immediately inform the Commission and the other Member States of measures that have been taken or are contemplated to minimise the recurrence of the incidents referred to in paragraph 1, including information on the underlying incidents.

4 The measures necessary for the implementation of this Article shall be adopted in accordance with the regulatory procedure referred to in Article 6(3).;

8. Article 9 shall be amended as follows:

(a) paragraph 8 shall be replaced by the following:

8. Decisions taken by the notified bodies in accordance with Annexes 2, 3 and 5 shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both Parties, for further periods of a maximum length of five years.;

(b) the following paragraph shall be added:

10. The measures designed to amend non-essential elements of this Directive, *inter alia* by supplementing it, relating to the means by which, in the light of technical progress and considering the intended users of the devices concerned, the information laid down in Annex 1 Section 15 may be set out shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 6(4).;

9. Article 9a shall be replaced by the following:

Article 9a

1 A Member State shall submit a duly substantiated request to the Commission and ask it to take the necessary measures in the following situations:

— that Member State considers that the conformity of a device or family of devices should be established, by way of derogation from the provisions of Article 9, by applying solely one of the given procedures chosen from among those referred to in Article 9,

— that Member State considers that a decision is required as to whether a particular product or product group falls within the definition of Article 1(2)(a), (c), (d) or (e).

Where measures are deemed necessary pursuant to the first subparagraph of this paragraph they shall be adopted in accordance with the regulatory procedure referred to in Article 6(3).

2 The Commission shall inform the Member States of the measures taken.;

10. Article 10 shall be amended as follows:

(a) in paragraph 1, the word 'his' shall be replaced by the word 'the'.

(b) the second subparagraph of paragraph 2 shall be replaced by the following:

> Member States may, however, authorise manufacturers to start the clinical investigations in question before the expiry of the 60-day period, provided that the ethics committee concerned has issued a favourable opinion with respect to the investigation programme in question including its review of the clinical investigation plan.;

(c) paragraph 3 shall be replaced by the following:

> 3. The Member States shall, if necessary, take the appropriate steps to ensure public health and public policy. Where a clinical investigation is refused or halted by a Member State, that Member State shall communicate its decision and the grounds therefor to all Member States and the Commission. Where a Member State has called for a significant modification or temporary interruption of a clinical investigation, that Member State shall inform the Member States concerned about its actions and the grounds for the actions taken.;

(d) the following paragraphs shall be added:

> 4. The manufacturer or his authorised representative shall notify the competent authorities of the Member States concerned of the end of the clinical investigation, with a justification in case of early termination. In the case of early termination of the clinical investigation on safety grounds this notification shall be communicated to all Member States and the Commission. The manufacturer or his authorised representative shall keep the report referred to in point 2.3.7 of Annex 7 at the disposal of the competent authorities.
>
> 5 Clinical investigations shall be conducted in accordance with the provisions of Annex 7. The measures designed to amend non-essential elements of this Directive relating to the provisions on clinical investigation

in Annex 7 shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 6(4).;

11. the following Articles shall be inserted:

Article 10a

1 Any manufacturer who, under his own name, places devices on the market in accordance with the procedure referred to in Article 9(2) shall inform the competent authorities of the Member State in which he has his registered place of business of the address of the registered place of business and the description of the devices concerned.

Member States may request to be informed of all data allowing for the devices to be identified together with the label and the instructions for use when the devices are put into service within their territory.

2 Where a manufacturer who places a device on the market under his own name does not have a registered place of business in a Member State, he shall designate a single authorised representative in the European Union.

For devices referred to in the first subparagraph of paragraph 1 the authorised representative shall inform the competent authority of the Member State in which he has his registered place of business of all details as referred to in paragraph 1.

3 The Member States shall on request inform the other Member States and the Commission of the details referred to in the first subparagraph of paragraph 1 given by the manufacturer or authorised representative.

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).

Article 10c

Where a Member State considers in relation to a given product or group of products that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited, restricted or subjected to particular requirements, it may take any necessary and justified transitional measures.

The Member State shall then inform the Commission and all the other Member States of the transitional measures, giving the reasons for its decision.

The Commission shall, whenever possible, consult the interested Parties and the Member States. The Commission shall adopt its opinion, indicating whether the national measures are justified or not. The Commission shall inform all the Member States and the consulted interested Parties.

When appropriate, the necessary measures designed to amend non-essential elements of this Directive, by supplementing it, relating to withdrawal from the market, prohibition of placing on the market and putting into service of a certain product or group of products or to restrictions or introduction of particular requirements therefor, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 6(4). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 6(5).;

12. Article 11 shall be amended as follows:

(a) in paragraph 2, the following subparagraph shall be added: 'When appropriate in the light of technical progress, the detailed measures necessary to ensure a consistent application of the criteria set out in Annex 8 to this Directive for the designation of bodies by the Member States shall be adopted in accordance with the regulatory procedure referred to in Article 6(3).';

(b) in paragraph 4, the words 'agent established in the Community' shall be replaced by the words 'authorised representative';

(c) the following paragraphs shall be added:

5. The notified body shall inform its competent authority about all certificates issued, modified, supplemented, suspended, withdrawn or refused and the other notified bodies within the scope of this Directive about certificates suspended, withdrawn or refused and, on request, about certificates issued. The notified body shall also make available, on request, all additional relevant information.

6 Where a notified body finds that pertinent requirements of this Directive have not been met or are no longer met by the manufacturer or that a certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer.

In the case of suspension or withdrawal of the certificate or of any restriction placed on it or in cases where an intervention of the competent authority may become necessary, the notified body shall inform its competent authority thereof.

The Member State shall inform the other Member States and the Commission.

7 The notified body shall, on request, supply all relevant information and documents, including budgetary documents, required to enable the Member State to verify compliance with the criteria laid down in Annex 8.;

13. Article 13 shall be replaced by the following:

Article 13

Without prejudice to Article 7

(a) where a Member State establishes that the CE marking has been affixed unduly or is missing in violation of this Directive, the manufacturer or his authorised representative established within the Community shall be obliged to end the infringement under conditions imposed by the Member State;

(b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the device in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.

Those provisions shall also apply where the CE marking has been affixed in accordance with the procedures in this Directive, but inappropriately, on products that are not covered by this Directive.;

14. Article 14 shall be amended as follows:

(a) the first paragraph shall be replaced by the following:

Any decision taken pursuant to this Directive

(a) to refuse or restrict the placing on the market or the putting into service of a device or the carrying out of clinical investigations;

or

(b) to withdraw devices from the market

shall state the exact grounds on which it is based. Such a decision shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the laws in force in the Member State in question and of the time limits to which such remedies are subject.;

(b) in the second paragraph the words ‘established in the Community’ shall be deleted;

15. Article 15 shall be replaced by the following:

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).;

16. the following Article shall be inserted:

Article 15a

Member States shall take appropriate measures to ensure that the competent authorities of the Member States cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly.

The Commission shall provide for the organisation of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive.

Without prejudice to the provisions of this Directive, cooperation may be part of initiatives developed at an international level.;

17. Annexes 1 to 7 shall be amended in accordance with Annex I to this Directive.

(**1**) OJ L 311, 28.11.2001, p. 67. Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p. 1)'

(**2**) Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility (OJ L 390, 31.12.2004, p. 24).';

(**3**) OJ L 157, 9.6.2006, p. 24.';

(**4**) Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37). Directive as last amended by the 2003 Act of Accession.';