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.

Article 2

Directive 93/42/EEC is hereby amended as follows:

1. Article 1 shall be amended as follows:

(a) paragraph 2 shall be amended as follows:

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

"medical device" means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, 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:;

(ii) in the third paragraph of point (d) the words 'are not' shall be replaced by the words 'shall not be';

(iii) the following points shall be added:

(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;

(l) "device subcategory" means a set of devices having common areas of intended use or common technology;

(m) "generic device group" means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

(n) "single use device" means a device intended to be used once only for a single patient.;

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

3. Where a device is intended to administer a medicinal product within the meaning of Article 1 of Directive 2001/83/EC[(5)], that device shall be governed by this Directive, without prejudice to the provisions of Directive 2001/83/EC with regard to the medicinal product.

If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by Directive 2001/83/EC. The relevant essential requirements of Annex I to this Directive shall apply as far as safety and performance-related device features are concerned.;

(c) in paragraph 4:

(i) the reference '65/65/EEC' shall be replaced by the reference '2001/83/EC';

(ii) the words 'that device must' shall be replaced by the words 'that device shall';

(d) in paragraph 4a:

(i) the reference '89/381/EEC' shall be replaced by the reference '2001/83/EC';

(ii) the words 'that device must' shall be replaced by the words 'that device shall';

(e) paragraph 5 shall be amended as follows:

(i) The introductory phrase shall be replaced by the following:

This Directive shall not apply to:;

(ii) point (c) shall be replaced by the following:

(c) 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;;

(iii) point (f) shall be replaced by the following:

(f) transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin, with the exception of devices referred to in paragraph 4a.;

(f) paragraph 6 shall be replaced by the following:

6. Where a device is intended by the manufacturer to be used in accordance with both the provisions on personal protective equipment in Council Directive 89/686/EEC[(6)] and this Directive, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled.

(g) paragraphs 7 and 8 shall be replaced by the following:

7. This Directive is a specific Directive within the meaning of Article 1(4) of Directive 2004/108/EC of the European Parliament and of the Council[(7)].

8 This Directive shall not affect the application of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation[(8)], nor of Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure[(9)].

2. in Article 3 the following paragraph shall be added:

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[(10)] 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 I to this Directive.

3. the second indent of Article 4(2) shall be replaced by the following:

— custom-made devices being placed on the market and put into service if they meet the conditions laid down in Article 11 in combination with Annex VIII; Class IIa, IIb and III devices shall be accompanied by the statement referred to in Annex VIII, which shall be available to the particular patient identified by name, an acronym or a numerical code.;

4. in Article 6(1) the reference ‘83/189/EEC’ shall be replaced by the reference

98/34/EC[(11)]

5. Article 7 shall be replaced by the following:

Article 7

1 The Commission shall be assisted by the Committee set up by Article 6(2) of Directive 90/385/EEC, hereinafter referred to as “the Committee”.

2 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.

3 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.

4 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.;

6. In Article 8 paragraph 2 shall be replaced by the following:

2. The Commission shall enter into consultation with the Parties concerned as soon as possible. Where, after such consultation, the Commission finds that:

a the measures are justified:

(i) it shall immediately so inform the Member State which took the measures and the other Member States. Where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the Parties concerned, bring the matter before the Committee referred to in Article 6(1) within two months if the Member State which has taken the decision intends to maintain it and shall initiate the advisory procedure referred to in Article 6(2);

(ii) when necessary in the interests of public health, appropriate measures designed to amend non-essential elements of this Directive relating to withdrawal from the market of devices referred to in paragraph 1 or to prohibition or restriction of their placement on the market or being put into service or to introduction of particular requirements in order for such products to be put on the market, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 7(4);

b the measures are unjustified, it shall immediately so inform the Member State which took the measures and the manufacturer or his authorised representative.;

7. In Article 9 paragraph 3 shall be replaced by the following:

3. Where a Member State considers that the classification rules set out in Annex IX require adaptation in the light of technical progress and any information which becomes available under the information system provided for in Article 10, it may submit a duly substantiated request to the Commission and ask it to take the necessary measures for adaptation of classification rules. The measures designed to amend non-essential elements of this Directive relating to adaptation of classification rules shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).;

8. Article 10 shall be amended as follows:

(a) in paragraph 2, the words ‘established in the Community’ shall be deleted;

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

3. After carrying out an assessment, if possible together with the manufacturer or his authorised representative, Member States shall, without prejudice to Article 8, 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.;

(c) the following paragraph shall be added:

4. Any appropriate measures to adopt procedures to implement this Article shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).;

9. Article 11 shall be amended as follows:

(a) in paragraphs 8 and 9 the words ‘established in the Community’ shall be deleted;

(b) in paragraph 11, the words ‘Annexes II and III’ shall be replaced by the words ‘Annexes II, III, V and VI’ and the words ‘for further periods of five years’ shall be replaced by the words ‘for further periods of a maximum length of five years’;

(c) the following paragraph shall be added:

14. The measures designed to amend non-essential elements of this Directive, 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 I Section 13.1 may be set out, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).;

10. Article 12 shall be amended as follows:

(a) the title shall be replaced by ‘Particular procedure for systems and procedure packs and procedure for sterilisation’;

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

3. Any natural or legal person who sterilises, for the purpose of placing on the market, systems or procedure packs referred to in paragraph 2 or other CE-marked medical devices designed by their manufacturers to be sterilised before use, shall, at his choice, follow one of the procedures referred to in Annex II or V. The application of the abovementioned Annexes and the intervention of the notified body are limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged. The person shall draw up a declaration stating that sterilisation has been carried out in accordance with the manufacturer's instructions.;

(c) in paragraph 4, the third sentence shall be replaced by the following:

The declarations referred to in paragraphs 2 and 3 shall be kept at the disposal of the competent authorities for a period of five years.;

11. The following Article shall be inserted:

Article 12a

Reprocessing of medical devices

The Commission shall, no later than 5 September 2010, submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community.

In the light of the findings of this report, the Commission shall submit to the European Parliament and to the Council any additional proposal it may deem appropriate in order to ensure a high level of health protection.

12. Article 13 shall be replaced by the following:

Article 13

Decisions with regard to classification and derogation clause

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:

a that Member State considers that the application of the classification rules set out in Annex IX requires a decision with regard to the classification of a given device or category of devices;

b that Member State considers that a given device or family of devices should, by way of derogation from the provisions of Annex IX, be classified in another class;

c that Member State considers that the conformity of a device or family of devices should, by way of derogation from Article 11, be established by applying solely one of the given procedures chosen from among those referred to in Article 11;

d that Member State considers that a decision is required as to whether a particular product or product group falls within one of the definitions in Article 1(2)(a) to (e).

The measures referred to in the first subparagraph of this paragraph shall, as appropriate, be adopted in accordance with the procedure referred to in Article 7(2).

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

13. Article 14 shall be amended as follows:

(a) in the second subparagraph of paragraph 1, the words ‘Classes IIb and III’ shall be replaced by the words ‘Classes IIa, IIb and III’;

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

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 the details referred to in paragraph 1.;

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

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.;

14. Article 14a shall be amended as follows:

(a) the second subparagraph of paragraph 1 shall be amended as follows:

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

(a) data relating to registration of manufacturers and authorised representatives and devices in accordance with Article 14 excluding data related to custom-made devices;;

(ii) the following point shall be added:

(d) data relating to clinical investigations referred to in Article 15;;

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

3. The measures necessary for the implementation of paragraphs 1 and 2 of this Article, in particular paragraph 1(d), shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).

(c) the following paragraph shall be added:

4. The provisions of this Article shall be implemented no later than 5 September 2012. The Commission shall, no later than 11 October 2012, evaluate the operational functioning and the added value of the databank. On the basis of this evaluation, the Commission shall, if appropriate, present proposals to the European Parliament and the Council or present draft measures in accordance with paragraph 3.;

15. Article 14b shall be replaced by the following:

Article 14b

Particular health monitoring measures

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 other Member States, 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 thereof.

When appropriate, the necessary measures designed to amend non-essential elements of this Directive, 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 in order for such products to be put on the market, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 7(4).;

16. Article 15 shall be amended as follows:

(a) paragraphs 1, 2 and 3 shall be replaced by the following:

1. In the case of devices intended for clinical investigations, the manufacturer or the authorised representative, established in the Community, shall follow the procedure referred to in Annex VIII and notify the competent authorities of the Member States in which the investigations are to be conducted by means of the statement mentioned in Section 2.2 of Annex VIII.

2 In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy.

Member States may however authorise manufacturers to commence the relevant clinical investigations before the expiry of the period of 60 days, insofar as the relevant ethics committee has issued a favourable opinion on the programme of investigation in question, including its review of the clinical investigation plan.

3 In the case of devices other than those referred to in paragraph 2, Member States may authorise manufacturers to commence clinical investigations immediately after the date of notification, provided that the ethics committee concerned has issued a favourable opinion on the programme of investigation in question including its review of the clinical investigation plan.;

(b) paragraphs 5, 6 and 7 shall be replaced by the following:

5. The clinical investigations must be conducted in accordance with the provisions of Annex X. The measures designed to amend non-essential elements of this Directive, inter alia by supplementing it, relating to the provisions on clinical investigation in Annex X shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).

6 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.

7 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 Section 2.3.7 of Annex X at the disposal of the competent authorities.;

17. Article 16 shall be amended as follows:

(a) the following subparagraph shall be added to paragraph 2:

When appropriate in the light of technical progress, the detailed measures necessary to ensure a consistent application of the criteria set out in Annex XI for the designation of bodies by the Member States shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).;

(b) in paragraph 4, the words ‘established in the Community’ shall be deleted;

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

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.;

18. in Article 18 point (a) shall be replaced by the following:

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

19. in Article 19(2), the words ‘established in the Community’ shall be deleted;

20. Article 20 shall be replaced by the following:

Article 20

Confidentiality

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 obligation 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 14;

b information to users sent out by the manufacturer, authorised representative or distributor in relation to a measure according to Article 10(3);

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 determination of the conditions under which other information may be made publicly available, and in particular for Class IIb and Class III devices to any obligation for manufacturers to prepare and make available a summary of the information and data related to the device, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).;

21. the following Article shall be inserted:

Article 20a

Cooperation

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.;

22. Annexes I to X shall be amended in accordance with Annex II to this Directive.

Article 3

In Article 1(2) of Directive 98/8/EC the following point shall be added:

(s) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[(12)].

Article 4

1 Member States shall adopt and publish by 21 December 2008 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those measures.

They shall apply those measures from 21 March 2010.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 5

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 6

This Directive is addressed to the Member States.

Done at Strasbourg, 5 September 2007.

For the European Parliament

The President

H.-G. PÖTTERING

For the Council

The President

M. LOBO ANTUNES

(**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.';

(**5**) 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 (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).';

(**6**) Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18). 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).'

(**7**) 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).

(**8**) OJ L 159, 29.6.1996, p. 1.

(**9**) OJ L 180, 9.7.1997, p. 22.'

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

(**11**) 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.'

(**12**) OJ L 331, 7.12.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).'