

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

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Directive 2007/47/EC of the European Parliament and of the Council
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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 derivatives 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 derivatives 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:

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 [], 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 [].

(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 [] 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 []

;

(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 [], 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 [] 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 [].

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 [], 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 [].

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 [] 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 []

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 [].

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 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 derivatives 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.

[] 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)"

[] 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).";

[] OJ L 157, 9.6.2006, p. 24.";

[] 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."

[] 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).";

[] 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)."

[] 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).

[] OJ L 159, 29.6.1996, p. 1.

[] OJ L 180, 9.7.1997, p. 22."

[] OJ L 157, 9.6.2006, p. 24."

[] 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."

[] 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)."

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ANNEX I

Annexes 1 to 7 to Directive 90/385/EEC shall be amended as follows:

1. Annex 1 shall be amended as follows:

(a) the following Section shall be inserted:

"5a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex 7."

;

(b) in Section 8, the fifth indent shall be replaced by the following:

- "— risks connected with ionising radiation from radioactive substances included in the device, in compliance with the protection requirements laid down in 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 [*] and 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 [**].

(c) in Section 9, seventh indent, the following phrase shall be added:

"For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification."

;

(d) Section 10 shall be replaced by the following:

"10. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC, and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 [***] on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from the EMA, acting particularly through its committee, on the quality and safety of the substance, including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial

consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of the incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the device.

When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance to the device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance to the device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.

(e) Section 14.2 shall be amended as follows:

(i) the first indent shall be replaced by the following:

- "— the name and address of the manufacturer and the name and address of the authorised representative, where the manufacturer does not have a registered place of business in the Community,"

;

(ii) the following indent shall be added:

- "— in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative."

;

(f) the following indent shall be added to the second paragraph of Section 15:

- "— date of issue or the latest revision of the instructions for use."

;

2. Annex 2 shall be amended as follows:

(a) in Section 2, the third paragraph shall be replaced by the following:

"This declaration shall cover one or more clearly identified devices by means of product name, product code or other unambiguous reference and must be kept by the manufacturer."

;

(b) in the second paragraph of Section 3.1, the first sentence of the fifth indent shall be replaced by the following:

- "— an undertaking by the manufacturer to institute and keep updated a post-marketing surveillance system including the provisions referred to in Annex 7."

;

(c) Section 3.2 shall be amended as follows:

(i) the following sentence shall be added to the second subparagraph:

"It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in point (c)."

;

(ii) the following indent shall be added to point (b):

- "— where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party."

;

(iii) the following indents shall be added to point (c):

- "— a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in Section 10 of Annex 1 and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,

- — the pre-clinical evaluation,

- — the clinical evaluation referred to in Annex 7."

;

(d) in Section 3.3, the last sentence of the second subparagraph shall be replaced by the following:

"The evaluation procedure shall include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes."

;

(e) Section 4.2 shall be amended as follows:

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

"The application shall describe the design, manufacture and performances of the product in question, and it must include the documents needed to assess whether the product conforms to the requirements of this Directive, and in particular Annex 2, Section 3.2, third paragraph, points (c) and (d)."

;

(ii) in the fourth indent of the second paragraph, the word "data" shall be replaced by the word "evaluation";

(f) in Section 4.3, the following paragraphs shall be added:

"In the case of devices referred to in Annex 1, Section 10, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA shall be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Annex 1, Section 10, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion shall be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA."

;

(g) in Section 5.2, the second indent shall be replaced by the following:

- "— the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, pre-clinical and clinical evaluation, post-market clinical follow-up plan and the results of the post-market clinical follow-up, if applicable, etc."

;

(h) Section 6.1 shall be replaced by the following:

"6.1. For at least 15 years from the last date of manufacture of the product, the manufacturer or his authorised representative shall keep available for the national authorities:

- the declaration of conformity,
- the documentation referred to in the second indent of Section 3.1, and in particular the documentation, data and records referred to in the second paragraph of Section 3.2,
- the amendments referred to in Section 3.4,
- the documentation referred to in Section 4.2,
- the decisions and reports of the notified body referred to in Sections 3.4, 4.3, 5.3 and 5.4."

;

(i) Section 6.3 shall be deleted;

(j) the following Section shall be added:

"7. Application to the devices referred to in Article 1(4a):

Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the

manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC."

;

3. Annex 3 shall be amended as follows:

(a) Section 3 shall be amended as follows:

(i) the first indent shall be replaced by the following:

- "— a general description of the type, including any variants planned, and its intended use (s),"

;

(ii) the fifth to eighth indents shall be replaced by the following:

- "— the results of design calculations, risk analysis, investigations and technical tests carried out, etc.,

- — a declaration stating whether or not the device incorporates, as an integral part, a substance or a human blood derivative as referred to in Section 10 of Annex 1 and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,

- — the pre-clinical evaluation,

- — the clinical evaluation referred to in Annex 7,

- — the draft instruction leaflet."

;

(b) the following paragraphs shall be added to Section 5:

"In the case of devices referred to in Annex 1, Section 10, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA shall be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Annex 1, Section 10, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion shall be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA."

;

(c) in Section 7.3, the words "five years from the manufacture of the last appliance" shall be replaced by the words "15 years from the manufacture of the last product";

(d) Section 7.4 shall be deleted;

4. Annex 4 shall be amended as follows:

(a) in Section 4, the words "post-marketing surveillance system" shall be replaced by the words "post-marketing surveillance system including the provisions referred to in Annex 7";

(b) Section 6.3 shall be replaced by the following:

"6.3. Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the harmonised standards referred to in Article 5, taking account of the specific nature of the product categories in question."

;

(c) the following Section shall be added:

"7. Application to the devices referred to in Article 1(4a):

Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC."

;

5. Annex 5 shall be amended as follows:

(a) in Section 2, second paragraph, the words "identified specimens of the product and shall be kept by the manufacturer" shall be replaced by the words "devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer";

(b) in the sixth indent of Section 3.1, the words "post-marketing surveillance system" shall be replaced by the words "post-marketing surveillance system including the provisions referred to in Annex 7";

(c) in Section 3.2(b), the following indent shall be added:

- "— where the manufacture and/or final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party."

;

(d) in Section 4.2, the following indent shall be inserted after the first indent:

- "— the technical documentation,"

;

(e) the following Section shall be added:

"6. Application to the devices referred to in Article 1(4a):

Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC."

;

6. Annex 6 shall be amended as follows:

(a) Section 2.1 shall be amended as follows:

(i) the first indent shall be replaced by the following two indents:

- "— the name and address of the manufacturer,

- — the information necessary for the identification of the product in question,"

;

(ii) in the third indent, the word "doctor" shall be replaced by the words "duly qualified medical practitioner";

(iii) the fourth indent shall be replaced by the following:

- "— the specific characteristics of the product revealed by the prescription,"

;

(b) Section 2.2 shall be replaced by the following:

"2.2. For devices intended for clinical investigations covered in Annex 7:

- data allowing the devices in question to be identified,

- the clinical investigation plan,

- the investigator's brochure,

- the confirmation of insurance of subjects,

- the documents used to obtain informed consent,

- a statement indicating whether or not the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 10 of Annex 1,

- the opinion of the ethics committee concerned and details of the aspects covered by its opinion,
- the name of the duly qualified medical practitioner or other authorised person and of the institution responsible for the investigations,
- the place, date of commencement and duration scheduled for the investigations,
- a statement affirming that the device in question complies with the essential requirements apart from the aspects constituting the object of the investigations and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient."

;

(c) in Section 3.1, the first paragraph shall be replaced by the following:

"For custom-made devices, documentation, indicating manufacturing site(s) and enabling the design, manufacture and performances of the product, including the expected performances, to be understood, so as to allow conformity with the requirements of this Directive to be assessed."

;

(d) in Section 3.2, the first paragraph shall be amended as follows:

(i) the first indent shall be replaced by the following:

- "— a general description of the product and its intended use,"

;

(ii) in the fourth indent, the words "a list of the standards" shall be replaced by the words "the results of the risk analysis and a list of the standards";

(iii) the following indent shall be inserted after the fourth indent:

- "— if the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 10 of Annex 1, the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance, or human blood derivative, taking account of the intended purpose of the device,"

;

(e) the following two sections shall be added:

"4. The information included in the declarations covered by this Annex shall be kept for a period of at least 15 years from the date of manufacture of the last product.

5. For custom-made devices, the manufacturer must undertake to review and to document experience gained in the post-production phase, including the provisions referred to in Annex 7, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them and the relevant corrective actions:

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or 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;

(ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in point (i) leading to systematic recall of devices of the same type by the manufacturer."

;

7. Annex 7 shall be amended as follows:

(a) Section 1 shall be replaced by the following:

"1. General provisions

1.1. As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 2 of Annex 1 under the normal conditions of use of the device and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 5 of Annex 1, must be based on clinical data. The evaluation of this data (hereinafter referred to as clinical evaluation), where appropriate taking account of any relevant harmonised standards, must follow a defined and

methodologically sound procedure based on:

1.1.1. Either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device where:

- there is demonstration of equivalence of the device to the device to which the data relates and,

- the data adequately demonstrate compliance with the relevant essential requirements;

1.1.2. Or a critical evaluation of the results of all the clinical investigations made,

1.1.3. Or a critical evaluation of the combined clinical data provided in 1.1.1 and 1.1.2.

1.2. Clinical investigations shall be performed unless it is duly justified to rely on existing clinical data.

1.3. The clinical evaluation and its outcome shall be documented. This documentation shall be included and/or fully referenced in the technical documentation of the device.

1.4. The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented.

1.5. Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk management output and under consideration of the specifics of the device/body interaction, the clinical performances intended and the claims of the manufacturer. Adequacy of demonstration of conformity with the essential requirements by performance evaluation, bench testing and pre-clinical evaluation alone has to be duly substantiated.

1.6. All data must remain confidential unless it is deemed essential that they be divulged."

(b) Section 2.3.5 shall be replaced by the following:

"2.3.5. All serious adverse events must be fully recorded and immediately notified to all competent authorities of the Member States in which the clinical investigation is being performed."

(c) In Section 2.3.6, the words "appropriately qualified medical specialist" shall be replaced by the words "duly qualified medical practitioner or authorised person".

[*] OJ L 159, 29.6.1996, p. 1.

[**] OJ L 180, 9.7.1997, p. 22.";

[***] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1). Regulation as last amended by Regulation (EC) No 1901/2006.";

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ANNEX II

Annexes I to X to Directive 93/42/EEC shall be amended as follows:

1. Annex I shall be amended as follows:

(a) Section 1 shall be replaced by the following:

"1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

This shall include:

- reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

- consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional,

disabled or other users)."

;

(b) the following Section shall be inserted:

"6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X."

;

(c) in Section 7.1, the following indent shall be added:

- "— where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand."

;

(d) Section 7.4. shall be replaced by the following:

"7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 [*] on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.

When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.

(e) Section 7.5 shall be replaced by the following:

"7.5. The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [**].

If parts of a device (or a device itself) intended to administer and/or remove medicines, body

liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.

If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

(f) in Section 8.2, the word "transferable" shall be replaced by the word "transmissible";

(g) the following Section shall be inserted:

"12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification."

;

(h) in Section 13.1, the first paragraph shall be replaced by the following:

"13.1. Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer."

;

(i) Section 13.3 shall be amended as follows:

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

"(a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community;"

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

"(b) the details strictly necessary to identify the device and the contents of the packaging especially for the users;"

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

"(f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;"

(j) Section 13.6 shall be amended as follows:

(i) the following subparagraph shall be added to point (h):

"If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;"

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

"(o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;"

(iii) the following point shall be added:

"(q) date of issue or the latest revision of the instructions for use."

;

(k) Section 14 shall be deleted.

2. Annex II shall be amended as follows:

(a) Section 2 shall be replaced by the following:

"2. The EC declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned meet the provisions of this Directive which apply to them.

The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer."

;

(b) in Section 3.1, second paragraph, the introductory part of the seventh indent shall be replaced by the following:

- "— an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:"

;

(c) Section 3.2 shall be amended as follows:

(i) the following paragraph shall be inserted after the first paragraph:

"It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in point (c)."

;

(ii) in point (b), the following indent shall be added:

- "— where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;"

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

"(c) the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular:

- a general description of the product, including any variants planned, and its intended use(s),
- the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to in Article 5 are not applied in full,
- the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed,
- if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer,
- a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in section 7.4 of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,
- a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Commission Directive 2003/32/EC [***],
- the solutions adopted as referred to in Annex I, Chapter I, Section 2,
- the pre-clinical evaluation,
- the clinical evaluation referred to in Annex X,
- the draft label and, where appropriate, instructions for use.

(d) the second paragraph of Section 3.3 shall be replaced by the following:

"The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an assessment, on a representative basis, of the documentation of the design of the product(s) concerned, an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the

manufacturing processes."

;

(e) in Section 4.3, the second and third paragraphs shall be replaced by the following:

"In the case of devices referred to in Annex I, Section 7.4, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion of the EMEA must be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.

In the case of devices manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the notified body must follow the procedures referred to in that Directive."

;

(f) in Section 5.2, the second indent shall be replaced by the following:

- "— the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, the solutions adopted as referred to in Annex I, Chapter I, Section 2, pre-clinical and clinical evaluation, post-market clinical follow-up plan and the results of the post-market clinical follow-up, if applicable, etc.,"

;

(g) Section 6.1 shall be amended as follows:

(i) the introductory part shall be replaced by the following:

"The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, keep at the disposal of the national authorities:"

;

(ii) the following phrase shall be added to the second indent:

"and in particular the documentation, data and records referred to in the second paragraph of Section 3.2,"

;

(h) Section 6.3 shall be deleted;

(i) Section 7 shall be replaced by the following:

"7. Application to devices in Classes IIa and IIb.

7.1. In line with Article 11(2) and (3), this Annex may apply to products in Classes IIa and IIb. Section 4, however, does not apply.

7.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3.2(c) for at least one representative sample for each device subcategory for compliance with the provisions of this Directive.

7.3. For devices in Class IIb the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3.2(c) for at least one representative sample for each generic device group for compliance with the provisions of this Directive.

7.4. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this

Directive. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

7.5. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 5."

;

(j) in Section 8, the words "Article 4(3) of Directive 89/381/EEC" shall be replaced by the words "Article 114(2) of Directive 2001/83/EC";

3. Annex III shall be amended as follows:

(a) Section 3 shall be replaced by the following:

"3. The documentation must allow an understanding of the design, the manufacture and the performances of the product and must contain the following items in particular:

- a general description of the type, including any variants planned, and its intended use(s),
- design drawings, methods of manufacture envisaged, in particular as regards sterilisation, and diagrams of components, sub-assemblies, circuits, etc.,
- the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product,
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements if the standards referred to in Article 5 have not been applied in full,
- the results of the design calculations, risk analysis, investigations, technical tests, etc. carried out,
- a statement indicating whether or not the device incorporates, as an integral part, a substance, or human blood derivative, referred to in Section 7.4 of Annex I, and the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance, or human blood derivative, taking account of the intended purpose of the device,
- a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC,
- the solutions adopted as referred to in Annex I, Chapter I, Section 2,
- the pre-clinical evaluation,
- the clinical evaluation referred to in Annex X,
- the draft label and, where appropriate, instructions for use."

;

(b) in Section 5, the second and third paragraphs shall be replaced by the following:

"In the case of devices referred to in Annex I, Section 7.4, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion of the EMEA must be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA.

In the case of devices manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the notified body must follow the procedures referred to in that Directive."

;

(c) Section 7.3 shall be replaced by the following:

"7.3. The manufacturer or his authorised representative must keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least five years after the last device has been manufactured. In the case of implantable devices, the period shall be at least 15 years after the last product has been manufactured."

;

(d) Section 7.4 shall be deleted;

4. Annex IV shall be amended as follows:

(a) in Section 1, the words "established in the Community" shall be deleted;

(b) in Section 3, the first paragraph shall be replaced by the following:

"3. The manufacturer must undertake to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:"

;

(c) Section 6.3 shall be replaced by the following:

"6.3. Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the harmonised standards referred to in Article 5, taking account of the specific nature of the product categories in question."

;

(d) in Section 7, the introductory part shall be replaced by the following:

"The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities:"

;

(e) in the introductory part of Section 8 the word "exemptions" shall be deleted;

(f) in Section 9, the words "Article 4(3) of Directive 89/381/EEC" shall be replaced by the words "Article 114(2) of Directive 2001/83/EC";

5. Annex V shall be amended as follows:

(a) Section 2 shall be replaced by the following:

"2. The EC declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Directive which apply to them.

The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and must be kept by the manufacturer."

;

(b) in the eighth indent of the second paragraph of Section 3.1, the introductory part shall be replaced by the following:

- "— an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them;"

;

(c) in point (b) of the third paragraph of Section 3.2, the following indent shall be added:

- "— where the manufacture and/or final inspection and testing of the products, or elements

thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;"

(d) in Section 4.2, the following indent shall be inserted after the first indent:

- "— the technical documentation,"

;

(e) in Section 5.1, the introductory part shall be replaced by the following:

"The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities:"

;

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

"6. Application to devices in Class IIa

In line with Article 11(2), this Annex may apply to products in Class IIa, subject to the following:

6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them.

6.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3 of Annex VII for at least one representative sample for each device subcategory for compliance with the provisions of this Directive.

6.3. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Directive. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

6.4. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.3."

;

(g) in Section 7, the words "Article 4(3) of Directive 89/381/EEC" shall be replaced by the words "Article 114(2) of Directive 2001/83/EC";

6. Annex VI shall be amended as follows:

(a) Section 2 shall be replaced by the following:

"2. The EC declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Directive which apply to them.

The manufacturer affixes the CE marking in accordance with Article 17 and draws up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and be kept by the manufacturer. The CE marking must be accompanied by the identification number of the notified body which performs the tasks referred to in this Annex."

;

(b) in the eighth indent of the second paragraph of Section 3.1, the introductory part shall be replaced by the following:

- "— an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:"

;

(c) in Section 3.2, the following indent shall be added:

- "— where the final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;"

(d) in Section 5.1, the introductory part shall be replaced by the following:

"The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities:"

;

(e) Section 6 shall be replaced by the following:

"6. Application to devices in Class IIa

In line with Article 11(2), this Annex may apply to products in Class IIa, subject to the following:

6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them.

6.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3 of Annex VII for at least one representative sample for each device subcategory for compliance with the provisions of this Directive.

6.3. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Directive. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

6.4. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.3."

;

7. Annex VII shall be amended as follows:

(a) Sections 1 and 2 shall be replaced by the following:

"1. The EC declaration of conformity is the procedure whereby the manufacturer or his authorised representative who fulfils the obligations imposed by Section 2 and, in the case of products placed on the market in a sterile condition and devices with a measuring function, the obligations imposed by Section 5 ensures and declares that the products concerned meet the provisions of this Directive which apply to them.

2. The manufacturer must prepare the technical documentation described in Section 3. The manufacturer or his authorised representative must make this documentation, including the declaration of conformity, available to the national authorities for inspection purposes for a period ending at least five years after the last product has been manufactured. In the case of implantable devices the period shall be at least 15 years after the last product has been manufactured."

;

(b) Section 3 shall be amended as follows:

(i) the first indent shall be replaced by the following:

- "— a general description of the product, including any variants planned and its intended use (s),"

;

(ii) the fifth indent shall be replaced by the following:

- "— in the case of products placed on the market in a sterile condition, description of the methods used and the validation report,"

;

(iii) the seventh indent shall be replaced by the following indents:

- "— the solutions adopted as referred to in Annex I, Chapter I, Section 2,
- — the pre-clinical evaluation,"

;

(iv) the following indent shall be inserted after the seventh indent:

- "— the clinical evaluation in accordance with Annex X,"

;

(c) in Section 4, the introductory part shall be replaced by the following:

"4. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. He shall notify the competent authorities of the following incidents immediately on learning of them:"

;

(d) in Section 5, the words "Annex IV, V or VI" shall be replaced by the words "Annex II, IV, V or VI";

8. Annex VIII shall be amended as follows:

(a) in Section 1, the words "established in the Community" shall be deleted;

(b) Section 2.1 shall be amended as follows:

(i) the following indent shall be inserted after the introductory phrase:

- "— the name and address of the manufacturer,"

;

(ii) the fourth indent shall be replaced by the following:

- "— the specific characteristics of the product as indicated by the prescription,"

;

(c) Section 2.2 shall be amended as follows:

(i) the second indent shall be replaced by the following:

- "— the clinical investigation plan,"

;

(ii) the following indents shall be inserted after the second indent:

- "— the investigator's brochure,
- — the confirmation of insurance of subjects,
- — the documents used to obtain informed consent,
- — a statement indicating whether or not the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 7.4 of Annex I,
- — a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC,"

;

(d) in Section 3.1, the first paragraph shall be replaced by the following:

"3.1. For custom-made devices, documentation, indicating manufacturing site(s) and allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of this Directive."

;

(e) Section 3.2 shall be replaced by the following:

"3.2. For devices intended for clinical investigations, the documentation must contain:

- a general description of the product and its intended use,
- design drawings, methods of manufacture envisaged, in particular as regards sterilisation, and diagrams of components, sub-assemblies, circuits, etc.,
- the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product,

- the results of the risk analysis and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Directive if the standards referred to in Article 5 have not been applied,
- if the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 7.4 of Annex I, the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,
- if the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the risk management measures in this connection which have been applied to reduce the risk of infection,
- the results of the design calculations, and of the inspections and technical tests carried out, etc.

The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation referred to in the first paragraph of this Section.

The manufacturer must authorise the assessment, or audit where necessary, of the effectiveness of these measures."

;

(f) Section 4 shall be replaced by the following:

"4. The information contained in the declarations concerned by this Annex shall be kept for a period of time of at least five years. In the case of implantable devices the period shall be at least 15 years."

;

(g) the following section shall be added:

"5. For custom-made devices, the manufacturer must undertake to review and document experience gained in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them and the relevant corrective actions:

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or 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;

(ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer."

;

9. Annex IX shall be amended as follows:

(a) Chapter I shall be amended as follows:

(i) in Section 1.4, the following sentence shall be added:

"Stand alone software is considered to be an active medical device."

;

(ii) Section 1.7 shall be replaced by the following:

"1.7. Central circulatory system

For the purposes of this Directive, "central circulatory system" means the following vessels: arteriae pulmonales, aorta ascendens, arcus aorta, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior."

;

(b) in Chapter II, Section 2, the following section shall be added:

"2.6. In calculating the duration referred to in Section 1.1 of Chapter I, continuous use means "an uninterrupted actual use of the device for the intended purpose". However where usage

of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered an extension of the continuous use of the device."

;

(c) Chapter III shall be amended as follows:

(i) the introductory phrase of the first paragraph of Section 2.1 shall be replaced by the following:

"All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I:"

;

(ii) Section 2.2 shall be replaced by the following:

"2.2. Rule 6

All surgically invasive devices intended for transient use are in Class IIa unless they are:

- intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,
- reusable surgical instruments, in which case they are in Class I,
- intended specifically for use in direct contact with the central nervous system, in which case they are in Class III,
- intended to supply energy in the form of ionising radiation in which case they are in Class IIb,
- intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb,
- intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in Class IIb."

;

(iii) in Section 2.3, the first indent shall be replaced by the following:

- "— either specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,"

;

(iv) in Section 4.1, first paragraph, the reference "65/65/EEC" shall be replaced by the reference "2001/83/EC";

(v) in Section 4.1, the second paragraph shall be replaced by the following:

"All devices incorporating, as an integral part, a human blood derivative are in Class III."

;

(vi) in Section 4.3, second paragraph, the following phrase shall be added:

"unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb."

;

(vii) in Section 4.4, the words "Non-active devices" shall be replaced by the word "Devices";

10. Annex X shall be amended as follows:

(a) Section 1.1 shall be replaced by the following:

"1.1. As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of Annex I, under the normal conditions of use of the device, and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 6 of Annex I, must be based on clinical data. The evaluation of this data, hereinafter referred to as "clinical evaluation", where appropriate taking account of any relevant harmonised standards, must follow a defined and methodologically sound procedure based on:

1.1.1. Either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where:

- there is demonstration of equivalence of the device to the device to which the data relates, and
- the data adequately demonstrate compliance with the relevant essential requirements.

1.1.2. Or a critical evaluation of the results of all clinical investigations made.

1.1.3. Or a critical evaluation of the combined clinical data provided in 1.1.1 and 1.1.2."

(b) The following Sections shall be inserted:

"1.1a In the case of implantable devices and devices in Class III clinical investigations shall be performed unless it is duly justified to rely on existing clinical data.

1.1b The clinical evaluation and its outcome shall be documented. This documentation shall be included and/or fully referenced in the technical documentation of the device.

1.1c The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented.

1.1d Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk management output and under consideration of the specifics of the device/body interaction, the clinical performances intended and the claims of the manufacturer. Adequacy of demonstration of conformity with the essential requirements by performance evaluation, bench testing and pre-clinical evaluation alone has to be duly substantiated."

;

(c) in Section 2.2, the first sentence shall be replaced by the following:

"Clinical investigations must be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the World Medical Assembly."

;

(d) Section 2.3.5 shall be replaced by the following:

"2.3.5. All serious adverse events must be fully recorded and immediately notified to all competent authorities of the Member States in which the clinical investigation is being performed."

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[*] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1). Regulation as last amended by Regulation (EC) No 1901/2006."

[**] OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850)."

[***] Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin (OJ L 105, 26.4.2003, p. 18)."
