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ANNEX X

CLINICAL EVALUATION

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 3 of Annex I under the normal conditions of use of the device and the evaluation of the undesirable side-effects must be based on clinical data in particular in the case of implantable devices and devices in Class III. Taking account of any relevant harmonized standards, where appropriate, the adequacy of the clinical data must be based on:

1.1.1. either a compilation of the relevant scientific literature currently available on the intended purpose of the device and the techniques employed as well as, if appropriate, a written report containing a critical evaluation of this compilation;

1.1.2. or the results of all the clinical investigations made, including those carried out in conformity with Section 2.

1.2. All the data must remain confidential, in accordance with the provisions of Article 20.

2. **Clinical investigations**

2.1. *Objectives*

The objectives of clinical investigation are:

— to verify that, under normal conditions of use, the performance of the devices conform to those referred to in Section 3 of Annex I, and

— to determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device.

2.2. *Ethical considerations*

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 41st World Medical Assembly in Hong Kong in 1989. It is mandatory that all measures relating to the protection of human subjects are carried out in the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.

2.3. *Methods*

2.3.1. Clinical investigations must be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims for the device; these investigations must include an adequate number of observations to guarantee the scientific validity of the conclusions.

2.3.2. The procedures used to perform the investigations must be appropriate to the device under examination.

2.3.3. Clinical investigations must be performed in circumstances similar to the normal conditions of use of the device.

2.3.4. All the appropriate features, including those involving the safety and performances of the device, and its effect on patients must be examined.

2.3.5. All adverse incidents such as those specified in Article 10 must be fully recorded and notified to the competent authority.

2.3.6. The investigations must be performed under the responsibility of a medical practitioner or another authorized qualified person in an appropriate environment.

The medical practitioner or other authorized person must have access to the technical and clinical data regarding the device.

2.3.7. The written report, signed by the medical practitioner or other authorized person responsible, must contain a critical evaluation of all the data collected during the clinical investigation.

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ANNEX XI

CRITERIA TO BE MET FOR THE DESIGNATION OF NOTIFIED BODIES

1. The notified body, its Director and the assessment and verification staff shall not be the designer, manufacturer, supplier, installer or user of the devices which they inspect, nor the authorized representative of any of these persons. They may not be directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This in no way precludes the possibility of exchanges of technical information between the manufacturer and the body.

2. The notified body and its staff must carry out the assessment and verification operations with the highest degree of professional integrity and the requisite competence in the field of medical devices and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of the verifications.

   Should the notified body subcontract specific tasks connected with the establishment and verification of the facts, it must first ensure that the subcontractor meets the provisions of the Directive and, in particular, of this Annex. The notified body shall keep at the disposal of the national authorities the relevant documents assessing the subcontractor's qualifications and the work carried out by the subcontractor under this Directive.

3. The notified body must be able to carry out all the tasks assigned to such bodies by one of Annexes II to VI and for which it has been notified, whether these tasks are carried out by the body itself or on its responsibility. In particular, it must have the necessary staff and possess the facilities needed to perform properly the technical and administrative tasks entailed in assessment and verification. ►M1 This presupposes the availability of sufficient scientific staff within the organisation who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Directive and, in particular, those set out in Annex I. ◄ It must also have access to the equipment necessary for the verifications required.

4. The notified body must have:

   — sound vocational training covering all the assessment and verification operations for which the body has been designated,

   — satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections,

   — the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

5. The impartiality of the notified body must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of the inspections.

6. The body must take out civil liability insurance, unless liability is assumed by the State under domestic legislation or the Member State itself carries out the inspections directly.

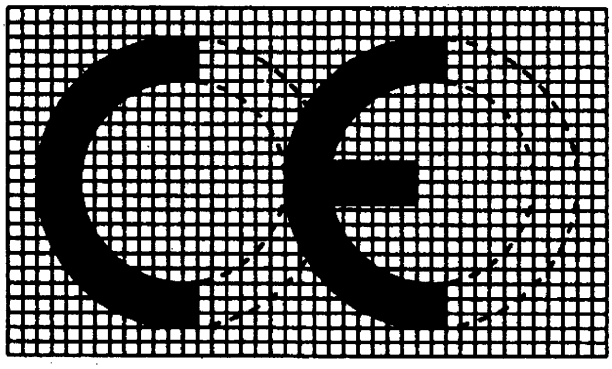
7. The staff of the notified body are bound to observe professional secrecy with regard to all information gained in the course of their duties (except *vis-à-vis* the competent administrative authorities of the State in which their activities are carried out) pursuant to this Directive or any provision of national law putting it into effect.

▼B

ANNEX XII

CE MARKING OF CONFORMITY

The CE conformity marking shall consist of the initials 'CE' taking the following form:



— If the marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

— The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

This minimum dimension may be waived for small-scale devices.

►B

COUNCIL DIRECTIVE

of 20 June 1990

on the approximation of the laws of the Member States relating to active implantable medical devices

(90/385/EEC)

(OJ L 189, 20.7.1990, p. 17)

Amended by:

		Official Journal		
		No	page	date
►M1	Council Directive 93/42/EEC of 14 June 1993	L 169	1	12.7.1993
►M2	Council Directive 93/68/EEC of 22 July 1993	L 220	1	30.8.1993
►M3	Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003	L 284	1	31.10.2003
►M4	Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007	L 247	21	21.9.2007

Corrected by:

►C1 Corrigendum, OJ L 7, 1.11.1994, p. 20 (90/385/EEC)

▼B

COUNCIL DIRECTIVE

of 20 June 1990

on the approximation of the laws of the Member States relating to active implantable medical devices

(90/385/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas in each Member State active implantable medical devices must give patients, users and other persons a high level of protection and achieve the intended level of performance when implanted in human beings;

Whereas several Member States have sought to ensure that level of safety by mandatory specifications relating both to the technical safety features and the inspection procedures for such devices; whereas those specifications differ from one Member State to another;

Whereas national provisions ensuring that safety level should be harmonized in order to guarantee the free movement of active implantable medical devices without lowering existing and justified levels of safety in the Member States;

Whereas harmonized measures must be distinguished from measures taken by Member States to manage the financing of public health and sickness insurance schemes directly or indirectly concerning such devices; whereas, therefore, such provisions do not affect the right of Member States to implement the abovementioned measures in compliance with Community law;

Whereas maintaining or improving the level of protection achieved in Member States constitutes one of this Directive's essential objectives as defined by the essential requirements;

Whereas rules governing active implantable medical devices can be confined to those provisions needed to satisfy the essential requirements; whereas, because they are essential, these requirements must replace corresponding national provisions;

Whereas, in order to facilitate proof of conformity with these essential requirements and to permit monitoring of that conformity, it is desirable to have Europe-wide harmonized standards in respect of the prevention of risks in connection with the design, manufacture and packaging of active implantable medical devices; whereas such standards harmonized at European level are drawn up by private-law bodies and must retain their status as non-mandatory texts; whereas, to that end, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as being the competent bodies to adopt harmonized standards in accordance with the general guidelines for cooperation between the Commission and these two bodies, signed on 13 November 1984; whereas, for the purposes of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted by either or both of these bodies, as instructed by the Commission pursuant to the provisions of Council Directive 83/189/EEC of 28 March 1983 laying

(1) OJ No C 14, 18.1.1989, p. 4.
(2) OJ No C 120, 16.5.1989, p. 75, and OJ No C 149, 18.6.1990.
(3) OJ No C 159, 26.6.1989, p. 47.

▼B

down a procedure for the provision of information in the field of technical standards and regulations (1), as last amended by Directive 88/182/EEC (2), and under the abovementioned general guidelines;

Whereas evaluation procedures have to be established and accepted by common accord between the Member States in accordance with Community criteria;

Whereas the specific nature of the medical sector makes it advisable to make provision for the notified body and the manufacturer or his agent established in the Community to fix, by common accord, the time limits for completion of the evaluation and verification operations for the conformity of devices,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to active implantable medical devices.

2. For the purposes of this Directive, the following definitions shall apply:

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(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;

▼B

(b) 'active medical device' means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;

(c) 'active implantable medical device' means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;

▼M4

(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;

(1) OJ No L 109, 26.4.1983, p. 8.
(2) OJ No L 81, 26.3.1988, p. 75.

▼M4

(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;

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(g) 'putting into service' means making available to the medical profession for implantation;

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(h) 'placing on the market' means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

(i) 'manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;

▼M4

(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.

3. Where an active implantable medical device is intended to administer a substance defined as a medicinal product within the meaning of Article 1 of Directive 2001/83/EC [1], that device shall be

[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)

▼M4

governed by this Directive, without prejudice to the provisions of Directive 2001/83/EC with regard to the medicinal product.

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.

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.

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

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.

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.

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 [2] 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.

[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).
[2] OJ L 157, 9.6.2006, p. 24.

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Article 4

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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.

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4. When a device is put into service, Member States may require the information described in sections 13, 14 and 15 of Annex 1 to be in their national language(s).

▼M2

5. (a) Where the devices are subject to other Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the devices are also presumed to conform to the provisions of the other Directives.

(b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying such devices; these documents, notices or instructions shall be accessible without it being necessary to destroy the packaging which keeps the device sterile.

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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.*

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Article 6

1. Where a Member State or the Commission considers that the harmonized standards referred to in Article 5 do not entirely meet the essential requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Standing Committee set up under Directive ►M4 98/34/EC [1] ◄, giving the reasons therefor. The Committee shall deliver an opinion without delay.

In the light of the opinion of the Committee, the Commission shall inform Member States of the measures to be taken with regard to the standards and the publication referred to in Article 5.

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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.

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Article 7

1. Where a Member State finds that the devices referred to in Article 1 (2) (c) and (d), correctly put into service and used in accordance with their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or their being put into service.

The Member State shall immediately inform the Commission of any such measure, indicating the reasons for its decision and, in particular, whether non-compliance with this Directive is due to:

(a) failure to meet the essential requirements referred to in Article 3, where the device does not meet in full or in part the standards referred to in Article 5;

(b) incorrect application of those standards;

(c) shortcomings in the standards themselves.

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

— the measures are justified, it shall immediately so inform the Member State which took the initiative 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

[1] 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.

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Member State which has taken the decision intends to maintain it and shall initiate the procedures referred to in Article 6 (1),

— the measures are unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorized representative established within the Community.

3. Where a device which does not comply bears the ►M2 CE marking ◄, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof.

4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

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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).

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Article 9

1. In the case of devices other than those which are custom-made or intended for clinical investigations, the manufacturer must, in order to affix the ►M2 CE marking ◄ at his own choice:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex 2; or

(b) follow the procedure relating to EC type-examination set out in Annex 3, coupled with:

(i) the procedure relating to EC verification set out in Annex 4, or

(ii) the procedure relating to the EC declaration of conformity to type set out in Annex 5.

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2. In the case of custom-made devices, the manufacturer must draw up the declaration provided for in Annex 6 before placing each device on the market.

3. Where appropriate, the procedures provided for in Annexes 3, 4 and 6 may be discharged by the manufacturer's authorized representative established in the Community.

4. The records and correspondence relating to the procedures referred to in paragraphs 1, 2 and 3 shall be in an official language of the Member State in which the said procedures will be carried out and/or in a language acceptable to the notified body defined in Article 11.

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5. During the conformity assessment procedure for a device, the manufacturer and/or the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with this Directive at an intermediate stage of manufacture.

6. Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer, or his authorized representative established in the Community, may apply to a body of his choice within the framework of the tasks for which the body has been notified.

7. The notified body may require, where duly justified, any information or data which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

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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.

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9. By derogation from paragraphs 1 and 2 the competent authorities may authorize, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 and 2 have not been carried out and the use of which is in the interest of protection of health.

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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).

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).

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

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Article 10

1. In the case of devices intended for clinical investigations, the manufacturer or ►M4 the ◄ authorized representative established in the Community shall, at least 60 days before the commencement of the investigations, submit the statement referred to in Annex 6 to the competent authorities of the Member State in which the investigations are to be conducted.

2. The manufacturer may commence the relevant clinical investigations 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 order.

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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.

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2a. The authorization referred to in the second subparagraph of paragraph 2 may be subject to approval by the competent authority.

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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.

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).

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

▼M4

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).

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Article 11

▼M2

1. Member States shall notify the Commission and the other Member State of the bodies which they have appointed to carry out the procedures referred to in Article 9 together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.

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2. Member States shall apply the minimum criteria, set out in Annex 8, for the designation of bodies. Bodies that satisfy the criteria fixed by the relevant harmonized standards shall be presumed to satisfy the relevant minimum criteria.

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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).

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3. A Member State that has notified a body shall withdraw that notification if it finds that the body no longer meets the criteria referred to in paragraph 2. It shall immediately inform the other Member States and the Commission thereof.

4. The notified body and the manufacturer or his ►M4 authorised representative ◄ shall fix, by common accord, the time limits for completion of the evaluation and verification operations referred to in Annexes 2 to 5.

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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.

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Article 12

1. Devices other than those which are custom made or intended for clinical investigations considered to meet the essential requirements referred to in Article 3 must bear the ►M2 CE marking ◄ of conformity.

2. The ►M2 CE marking ◄ of conformity, as shown in Annex 9, must appear in a visible, legible and indelible form on the sterile pack and, where appropriate, on the sales packaging, if any, and on the instruction leaflet.

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It must be followed by the identification number of the notified body responsible for implementation of the procedures set out in Annexes 2, 4 and 5.

3. The affixing of markings on the devices which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE marking is not hereby reduced.

▼M4

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.

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Article 14

▼M4

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.

▼M1

In the event of a decision as referred to in the previous paragraph the manufacturer, or his authorized representative ►M4 ———— ◄, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measures to be taken.

▼M4

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).

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.

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Article 16

1. Before 1 July 1992, Member States shall adopt and publish the laws, regulations and administrative provisions necessary in order to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply such provisions from 1 January 1993.

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

3. Member States shall, for the period up to 31 December 1994, permit the placing on the market and putting into service of devices complying with national rules in force in their territory on 31 December 1992.

Article 17

This Directive is addressed to the Member States.

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ANNEX 1

ESSENTIAL REQUIREMENTS

I. GENERAL REQUIREMENTS

1. The devices must be designed and manufactured in such a way that, when implanted under the conditions and for the purposes laid down, their use does not compromise the clinical condition or the safety of patients. They must not present any risk to the persons implanting them or, where applicable, to other persons.

2. The devices must achieve the performances intended by the manufacturer, viz. be designed and manufactured in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a) as specified by him.

3. The characteristics and performances referred to in sections 1 and 2 must not be adversely affected to such a degree that the clinical condition and safety of the patients or, as appropriate, of other persons are compromised during the lifetime of the device anticipated by the manufacturer, where the device is subjected to stresses which may occur during normal conditions of use.

4. The devices must be designed, manufactured and packed in such a way that their characteristics and performances are not adversely affected in the storage and transport conditions laid down by the manufacturer (temperature, humidity, etc.).

5. Any side effects or undesirable conditions must constitute acceptable risks when weighed against the performances intended.

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

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II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

6. The solutions adopted by the manufacturer for the design and construction of the devices must comply with safety principles taking account of the generally acknowledged state of the art.

7. Implantable devices must be designed, manufactured and packed in a non-reusable pack according to appropriate procedures to ensure they are sterile when placed on the market and, in the storage and transport conditions stipulated by the manufacturer, remain so until the packaging is removed and they are implanted.

8. Devices must be designed and manufactured in such a way as to remove or minimize as far as possible:

   — the risk of physical injury in connection with their physical, including dimensional, features,

   — risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,

   — risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration,

   — risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment,

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   — 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 [1]and Council Directive 97/43/Euratom of 30 June 1997

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

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on health protection of individuals against the dangers of ionising radiation in relation to medical exposure [1],

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— risks which may arise where maintenance and calibration are impossible, including:

— excessive increase of leakage currents,

— ageing of the materials used,

— excess heat generated by the device,

— decreased accuracy of any measuring or control mechanism.

9. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in I. 'General requirements', with particular attention being paid to:

— the choice of materials used, particularly as regards toxicity aspects,

— mutual compatibility between the materials used and biological tissues, cells and body fluids, account being taken of the anticipated use of the device,

— compatibility of the devices with the substances they are intended to administer,

— the quality of the connections, particularly in respect of safety,

— the reliability of the source of energy,

— if appropriate, that they are leakproof,

— proper functioning of the programming and control systems, including software. ►M4 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. ◄

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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 (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 [2] 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 EMEA 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 EMEA, 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 EMEA 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

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

[2] 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.

▼M4

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.

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11. The devices and, if appropriate, their component parts must be identified to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices and their component parts.

12. Devices must bear a code by which they and their manufacturer can be unequivocably identified (particularly with regard to the type of device and year of manufacture); it must be possible to read this code, if necessary, without the need for a surgical operation.

13. When a device or its accessories bear instructions required for the operation of the device or indicate operating or adjustment parameters, by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

14. Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:

14.1. On the sterile pack:

— the method of sterilization,
— an indication permitting this packaging to be recognized as such,
— the name and address of the manufacturer,
— a description of the device,
— if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations',
— if the device is custom-made, the words 'custom-made device',
— a declaration that the implantable device is in a sterile condition,
— the month and year of manufacture,
— an indication of the time limit for implanting a device safely.

14.2. On the sales packaging:

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— 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,

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— a description of the device,
— the purpose of the device,
— the relevant characteristics for its use,
— if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations',
— if the device is custom-made, the words: 'custom-made device',
— a declaration that the implantable device is in a sterile condition,
— the month and year of manufacture,
— an indication of the time limit for implanting a device safely,
— the conditions for transporting and staring the device ,

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