

EC Directive on Medical Devices

[*MMC note:* This text was adopted as representing the Common Position of the EC member states on 8 February 1993. It has not yet been published in the Official Journal of the EC. The annexes to the Directive are not included in this appendix.]

COUNCIL DIRECTIVE 93/.../EEC

of

concerning medical devices

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 Commission¹,

In co-operation with the European Parliament²,

Having regard to the Opinion of the Economic and Social Committee³,

Whereas measures should be adopted in the context of the internal market; whereas the internal market is an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas the content and scope of the laws, regulations and administrative provisions in force in the Member States with regard to the safety, health protection and performance characteristics of medical devices are different; whereas the certification and inspection procedures for such devices differ from one Member State to another; whereas such disparities constitute barriers to trade within the Community;

Whereas the national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices should be harmonized in order to guarantee the free movement of such devices within the internal market;

Whereas the harmonized provisions must be distinguished from the measures adopted by the Member States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices; whereas, therefore, these provisions do not affect the ability of the Member States to implement the abovementioned measures provided Community law is complied with;

Whereas medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of this Directive;

¹OJ No C 237, 12.9.1991 and OJ No C 251, 28.9.1992, p 40.

²Opinion delivered on 13 May 1992 (not yet published in the Official Journal).

³OJ No C 79, 30.3.1992, p 1.

Whereas certain medical devices are intended to administer medicinal products within the meaning of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products¹; whereas, in such cases the placing on the market of the medical device as a general rule is governed by the present Directive and the placing on the market of the medicinal product is governed by Directive 65/65/EEC; 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 unit which is intended exclusively for use in the given combination and which is not reusable, that single-unit product shall be governed by Directive 65/65/EEC; whereas a distinction must be drawn between the abovementioned devices and medical devices incorporating, inter alia, substances which, if used separately, may be considered to be a medicinal substance within the meaning of Directive 65/65/EEC; in such cases, if the substances incorporated in the medical devices are liable to act upon the body with action ancillary to that of the device, the placing of the devices on the market is governed by this Directive; whereas, in this context, the safety, quality and usefulness of the substances must be verified by analogy with the appropriate methods specified in Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products²;

Whereas the essential requirements and other requirements set out in the Annexes to this Directive, including any reference to 'minimizing' or 'reducing' risk must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety;

Whereas, in accordance with the principles set out in the Council Resolution of 7 May 1985 concerning a new approach to technical harmonization and standardization³, rules regarding the design and manufacture of medical devices must be confined to the provisions required to meet the essential requirements; whereas, because they are essential, such requirements should replace the corresponding national provisions; whereas the essential requirements should be applied with discrimination to take account of the technological level existing at the time of design and of technical and economic considerations compatible with a high level of protection of health and safety;

Whereas Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices⁴ is the first case of application of the new approach to the field of medical devices; whereas in the interest of uniform Community rules applicable to all medical devices, this Directive is based largely on the provisions of Directive 90/385/EEC; whereas for the same reasons Directive 90/385/EEC must be amended to insert the general provisions laid down in this Directive;

Whereas the electromagnetic compatibility aspects form an integral part of the safety of medical devices; whereas this Directive should contain specific rules on this subject with regard to Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility⁵;

Whereas this Directive should include requirements regarding the design and manufacture of devices emitting ionizing radiation; whereas this Directive does not affect the authorization required by Council Directive 80/836/Euratom of 15 July 1980 amending the Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation⁶, nor application of Council Directive 84/466/EURATOM of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment⁷; whereas Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the

¹OJ No L 22, 9.6.1965, p 369/65. Directive as last amended by Directive 92/27/EEC, (OJ No L 113, 30.4.1992, p 8).

²OJ No L 147, 9.6.1975, p 1. Directive as last amended by Directive 91/507/EEC, (OJ No L 270, 26.1.1991, p 32).

³OJ No C 136, 4.6.1985, p 1.

⁴OJ No L 189, 20.7.1990, p 17.

⁵OJ No L 139, 23.5.1989, p 19. Directive as last amended by Directive 92/31/EEC (OJ No L 126, 23.5.1991, p 1).

⁶OJ No L 246, 17.9.1980, p 1. Directive as last amended by Directive 84/467/EURATOM (OJ No L 265, 5.10.1984, p 4).

⁷OJ No L 265, 5.10.1984, p 1.

safety and health of workers at work¹ and the specific directives on the same subject should continue to apply;

Whereas, in order to demonstrate conformity with these essential requirements and to enable conformity to be verified, it is desirable to have harmonized European standards to protect against the risks associated with the design, manufacture and packaging of medical devices; whereas such harmonized European standards are drawn up by private-law bodies and should retain their status as non-mandatory texts; whereas, to this end, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines on co-operation between the Commission and these two bodies signed on 13 November 1984;

Whereas, for the purpose of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted, on a mandate from the Commission, by either or both of these bodies in accordance with Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations², and pursuant to the abovementioned general guidelines; whereas with regard to possible amendment of the harmonized standards, the Commission should be assisted by the Committee set up under Directive 83/189/EEC; whereas the measures to be taken must be defined in line with procedure I, as laid down in Council Decision 87/373/EEC³; whereas, for specific fields, what already exists in the form of European Pharmacopoeia monographs should be incorporated within the framework of this Directive; whereas, therefore, several European Pharmacopoeia monographs may be considered equal to the abovementioned harmonized standards;

Whereas, in Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives⁴, the Council has laid down harmonized conformity assessment procedures; whereas the application of these modules to medical devices enables the responsibility of manufacturers and notified bodies to be determined during conformity assessment procedures on the basis of the type of devices concerned; whereas the details added to these modules are justified by the nature of the verification required for medical devices;

Whereas it is necessary, essentially for the purpose of the conformity assessment procedures, to group the devices into four product classes; whereas 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; whereas the conformity assessment procedures for Class I devices can be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products; whereas, for Class IIa devices, the intervention of a notified body should be compulsory at the production stage; whereas, for devices falling within Classes IIb and III which constitute a high risk potential, inspection by a notified body is required with regard to the design and manufacture of the devices; whereas Class III is set aside for the most critical devices for which explicit prior authorization with regard to conformity is required for them to be placed on the market;

Whereas in cases where the conformity of the devices can be assessed under the responsibility of the manufacturer the competent authorities must be able, particularly in emergencies, to contact a person responsible for placing the device on the market and established in the Community, whether the manufacturer or another person established in the Community and designated by the manufacturer for the purpose;

Whereas medical devices should, as a general rule, bear the EC mark to indicate their conformity with the provisions of this Directive to enable them to move freely within the Community and to be put into service in accordance with their intended purpose;

¹OJ No L 183, 29.6.1989, p 1.

²OJ No L 109, 26.4.1983, p 8. Directive as last amended by Commission Directive 92/400/EEC (OJ No L 221, 6.8.1992, p 55).

³OJ No L 197, 18.7.1987, p 33.

⁴OJ No L 380, 31.12.1990, p 13.

Whereas, in the fight against AIDS and in the light of the conclusions of the Council adopted on 16 May 1989 regarding future activities on AIDS prevention and control at Community level¹, medical devices used for protection against the HIV virus must afford a high level of protection; whereas the design and manufacture of such products should be verified by a notified body;

Whereas the classification rules generally enable medical devices to be appropriately classified; whereas, in view of the diverse nature of the devices and technological progress in this field, steps must be taken to include amongst the implementing powers conferred on the Commission the decisions to be taken with regard to the proper classification or reclassification of the devices or, where appropriate, the adjustment of the classification rules themselves; whereas since these issues are closely connected with the protection of health, it is appropriate that these decisions should come under procedure IIIa, as provided for in Decision 87/373/EEC;

Whereas the confirmation of compliance with the essential requirements may mean that clinical investigations have to be carried out under the responsibility of the manufacturer; whereas, for the purpose of carrying out the clinical investigations, appropriate means have to be specified for the protection of public health and public order;

Whereas the protection of health and the associated controls may be made more effective by means of medical device vigilance systems which are integrated at Community level;

Whereas this Directive covers the medical devices referred to in Council Directive 76/764/EEC of 27 July 1976 on the approximation of the laws of the Member States on clinical mercury-in-glass, maximum reading thermometers², whereas the abovementioned Directive must therefore be repealed; whereas for the same reasons Council Directive 84/539/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to electro-medical equipment used in human or veterinary medicine³ must be amended,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Definitions, scope

1. This Directive shall apply to medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as medical devices in their own right. Both medical devices and accessories shall hereinafter be termed devices.

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

(a) 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used on human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

¹OJ No C 185, 22.7.1989, p 8.

²OJ No L 262, 27.9.1976, p 139. Directive as last amended by Directive 84/414/EEC (OJ No L 228, 25.8.1984, p 25).

³OJ No L 300, 19.11.1984, p 179. Directive as amended by the Act of Accession of Spain and Portugal (OJ No L 302, 15.11.1985, p 1).

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) 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;
- (c) 'device used for in vitro diagnosis' means any device which is a reagent, reagent product, kit, instrument, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of samples derived from the human body with a view to providing information on the physiological state, state of health or disease, or congenital abnormality thereof;
- (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.

The abovementioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so.

Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are not 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 investigations as referred to in section 2.1 of Annex X in an adequate human clinical environment.

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

- (f) '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 sub-paragraph does not apply to the person who, while not a manufacturer within the meaning of the first sub-paragraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;

- (g) '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 materials;
- (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) 'putting into service' means the stage at which a device is ready for use on the Community market for the first time for its intended purpose;

3. Where a device is intended to administer a medicinal product within the meaning of Article 1 of Directive 65/65/EEC, that device shall be governed by the present directive, without prejudice to the provisions of Directive 65/65/EEC 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 unit which is intended exclusively for use in the given combination and which is not reusable, that single unit product shall be governed by Directive 65/65/EEC. The relevant essential requirements of Annex I of the present directive shall apply as far as safety and performance related device features are concerned.

4. Where a 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 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, that device must be assessed and authorized in accordance with this Directive.

5. This Directive does not apply to:

(a) in-vitro diagnostic devices;

(b) active implantable devices covered by Directive 90/385/EEC;

(c) medicinal products covered by Directive 65/65/EEC;

(d) cosmetic products covered by Directive 76/768/EEC¹;

(e) human blood, human blood products, human 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;

(f) transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin;

(g) transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

6. This Directive does not apply to personal protective equipment covered by Directive 89/686/EEC. In deciding whether a product falls under that Directive or the present Directive, particular account shall be taken of the principal intended purpose of the product.

7. This Directive is a specific Directive within the meaning of Article 2(2) of Directive 89/336/EEC.

8. This Directive does not affect the application of Directive 80/836/EURATOM, nor of Directive 84/466/EURATOM.

Article 2

Placing on the market and putting into service

Member States shall take all necessary steps to ensure that devices may be placed on the market and put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose.

¹OJ No L 262, 27.9.1976, p 169. Directive as last amended by Commission Directive 92/86/EEC (OJ No L 325, 11.11.1992, p 18).

Article 3

Essential requirements

The devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned.

Article 4

Free movement, devices intended for special purposes

1. Member States shall not create any obstacles to the placing on the market or the putting into service within their territory of devices bearing the CE marking provided for in Article 17 which indicate that they have been the subject of an assessment of their conformity in accordance with the provisions of Article 11.

2. Member States shall not create any obstacles to:

— devices intended for clinical investigation being made available to medical practitioners or authorized persons for that purpose if they meet the conditions laid down in Article 15 and in Annex VIII;

— 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.

These devices shall not bear the CE marking.

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

4. Member States may require the information, which must be made available to the user and the patient in accordance with Annex I, point 13, to be in their national language(s) or in another Community language, when a device reaches the final user, regardless of whether it is for professional or other use.

5. 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 also fulfil the provisions of the other Directives.

However, should one or more of these directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate that the devices fulfil the provisions only of those directives applied by the manufacturer. In this case, the particulars of these directives, 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.

Article 5

Reference to standards

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 harmonized standards the references of which have been published in the Official Journal of the European Communities; Member States shall publish the references of such national standards.

2. For the purposes of this Directive, reference to harmonized standards also includes the monographs of the European Pharmacopoeia notably on surgical sutures and 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 Communities.

3. If a Member State or the Commission considers that the harmonized standards do not entirely meet the essential requirements referred to in Article 3, the measures to be taken by the Member States with regard to these standards and the publication referred to in paragraph 1 of this Article shall be adopted by the procedure defined in Article 6(2).

Article 6

Committee on Standards and Technical Regulations

1. The Commission shall be assisted by the committee set up by Article 5 of Directive 83/189/EEC.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

Article 7

Committee on Medical Devices

1. The Commission shall be assisted by the committee set up by Article 6(2) of Directive 90/385/EEC.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

3. The committee may examine any question connected with implementation of this Directive.

Article 8

Safeguard clause

1. Where a Member State ascertains that the devices referred to in Article 4(1) and (2) second indent, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision and, in particular, whether noncompliance with this Directive is due to:

- (a) failure to meet the essential requirements referred to in Article 3;
- (b) incorrect application of the standards referred to in Article 5, insofar as it is claimed that the standards have been applied;
- (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 Member State which has taken the decision intends to maintain it and shall initiate the procedures referred to in Article 6;

— 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 non-complying device bears the 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.

Article 9

Classification

1. Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX.

2. In the event of a dispute between the manufacturer and the notified body concerned, resulting from the application of the classification rules, the matter shall be referred for decision to the competent authority to which the notified body is subject.

3. The classification rules set out in Annex IX may be adapted in accordance with the procedure referred to in Article 7(2) in the light of technical progress and any information which becomes available under the information system provided for in Article 10.

Article 10

Information on incidents occurring following placing of devices on the market

1. Member States shall take the necessary steps to ensure that any information brought to their knowledge, in accordance with the provisions of this Directive, regarding the incidents mentioned below involving a Class I, IIa, IIb or III device is recorded and evaluated centrally:
 - (a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inaccuracies 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;
 - (b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph (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 authorized representative established in the Community, is also informed of the incident.
3. After carrying out an assessment, if possible together with the manufacturer, Member States shall, without prejudice to Article 8, immediately inform the Commission and the other Member States of the incidents referred to in paragraph 1 for which relevant measures have been taken or are contemplated.

Article 11

Conformity assessment procedures

1. In the case of devices falling within Class III, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either:
 - (a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance), or
 - (b) follow the procedure relating to EC type-examination set out in Annex III, coupled with:
 - (i) the procedure relating to EC verification set out in Annex IV,or
 - (ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance).
2. In the case of devices falling within Class IIa, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure relating to the EC declaration of conformity set out in Annex VII, coupled with either:
 - (a) the procedure relating to EC verification set out in Annex IV,or

(b) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance),

or

(c) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance).

Instead of applying these procedures, the manufacturer may also follow the procedure referred to in paragraph 3(a).

3. In the case of devices falling within Class IIb, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); in this case, point 4 of Annex II is not applicable, or

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

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

or

(ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance),

or

(iii) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance).

4. The Commission shall, no later than five years from the date of implementation of this Directive, submit a report to the Council on the operation of the provisions referred to in Article 10(1), Article 15(1), in particular in respect of class I and class IIa devices, and on the operation of the provisions referred to in Annex II section 4.3 second and third subparagraphs and in Annex III section 5 second and third subparagraphs of this Directive, accompanied, if necessary, by appropriate proposals.

5. In the case of devices falling within Class I, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex VII and draw up the EC declaration of conformity required before placing the device on the market.

6. In the case of custom-made devices, the manufacturer shall follow the procedure referred to in Annex VIII and draw up the statement set out in that Annex before placing each device on the market.

Member States may require that the manufacturer shall submit to the competent authority a list of such devices which have been put into service in their territory.

7. 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.

8. The manufacturer may instruct his authorized representative established in the Community to initiate the procedures provided for in Annexes III, IV, VII and VIII.

9. 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.

10. 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.

11. Decisions taken by the notified bodies in accordance with Annexes II and III 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 five years.

12. The records and correspondence relating to the procedures referred to in paragraphs 1 to 6 shall be in an official language of the Member State in which the procedures are carried out and/or in another Community language acceptable to the notified body.

13. By derogation from paragraphs 1 to 6, 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 to 6 have not been carried out and the use of which is in the interest of protection of health.

Article 12

Particular procedure for Systems and procedure packs

1. By way of derogation from Article 11 this Article shall apply to systems and procedure packs.
2. Any natural or legal person who puts devices bearing the CE marking together within their intended purpose and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack, shall draw up a declaration by which he states that:
 - (a) he has verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions, and
 - (b) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers, and
 - (c) the whole activity is subjected to appropriate methods of internal control and inspection.

Where the conditions above are not met, as in cases where the system or procedure pack incorporate devices which do not bear a CE-marking or where the chosen combination of devices is not compatible in view of their original intended use, the system or procedure pack shall be treated as a device in its own right and as such be subjected to the relevant procedure under Article 11.

3. Any natural or legal person who sterilizes, 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 sterilized before use, shall, at his choice, follow one of the procedures referred to in Annexes IV, V or VI. The application of the above mentioned Annexes and the intervention of the notified body are limited to the aspects of the procedure relating to the obtaining of sterility. The person shall draw up a declaration stating that sterilization has been carried out in accordance with the manufacturer's instructions.

4. The products referred to in paragraphs 2 and 3 themselves shall not bear an additional CE-marking. They shall be accompanied by the information referred to in point 13 of Annex I which includes, where appropriate, the information supplied by the manufacturers of the devices which have been put together. The declaration referred to in paragraphs 2 and 3 above shall be kept at the disposal of competent authorities for a period of five years.

Article 13

Decisions with regard to classification, derogation clause

1. Where a Member State considers that:

(a) 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,

or

(b) a given device or family of devices should be classified, by way of derogation from the provisions of Annex IX, in another class,

or

(c) the conformity of a device or family of devices should be established, by way of derogation from the provisions of Article 11, by applying solely one of the given procedures chosen from among those referred to in Article 11,

it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures. These measures shall 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 and, where appropriate, publish the relevant parts of these measures in the Official Journal of the European Communities.

Article 14

Registration of persons responsible for placing devices on the market

1. Any manufacturer who, under his own name, places devices on the market in accordance with the procedures referred to in Article 11(5) and (6) and any other natural or legal person engaged in the activities referred to in Article 12 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.

2. Where a manufacturer who places devices referred to in paragraph 1 on the market under his own name does not have a registered place of business in a Member State, he shall designate the person(s) responsible for marketing them who is (are) established in the Community. These persons shall inform the competent authorities of the Member State in which they have their registered place of business of the address of the registered place of business and the category of devices concerned.

3. The Member States shall on request inform the other Member States and the Commission of the details referred to in paragraphs 1 and 2.

Article 15

Clinical investigation

1. In the case of devices intended for clinical investigations, the manufacturer, or his authorized 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.

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 sixty 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 authorize 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.

3. In the case of devices other than those referred to in the second paragraph, Member States may authorize manufacturers to commence clinical investigations, immediately after the date of notification, provided that the ethics committee concerned has delivered a favourable opinion with regard to the investigational plan.

4. The authorization referred to in paragraph 2 second subparagraph and paragraph 3 above, may be made subject to authorization from the competent authority.

5. The clinical investigations must be conducted in accordance with the provisions of Annex X. The provisions of Annex X may be adjusted in accordance with the procedure laid down in Article 7(2).

6. The Member States shall, if necessary, take the appropriate steps to ensure public health and public policy.

7. The manufacturer or his authorized representative established in the Community shall keep the report referred to in point 2.3.7 of Annex X at the disposal of the competent authorities.

8. The provisions of paragraphs 1 and 2 do not apply where the clinical investigations are conducted using devices which are authorized in accordance with Article 11 to bear the EC marking unless the aim of these investigations is to use the devices for a purpose other than that referred to in the relevant conformity assessment procedure. The relevant provisions of Annex X remain applicable.

Article 16

Notified bodies

1. The Member States shall notify the Commission and other Member States of the bodies which they have designated for carrying out the tasks pertaining to the procedures referred to in Articles 11 and 18 and the specific tasks for which the bodies have been designated. The Commission shall assign identification numbers to these bodies, hereinafter referred to as 'notified bodies'.

The Commission shall publish a list of the notified bodies, together with the identification numbers it has allocated to them and the tasks for which they have been notified, in the Official Journal of the European Communities. It shall ensure that the list is kept up to date.

2. Member States shall apply the criteria set out in Annex XI for the designation of bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonized standards shall be presumed to meet the relevant criteria.

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 authorized representative established in the Community, shall lay down, by common accord, the time limits for completion of the assessment and verification operations referred to in Annexes II to VI.

Article 17

CE marking

1. Devices, other than devices which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Article 3 must bear the EC marking of conformity when they are placed on the market.

2. The CE marking of conformity, as shown in Annex XII, must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use. Where applicable the EC mark of conformity must also appear on the sales packaging.

It shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes II, IV, V and VI.

3. It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking. Any other mark may be affixed to the device, to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE marking is not thereby reduced.

Article 18

Wrongly affixed CE marking

Without prejudice to Article 8:

- (a) Where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized 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 product in question or to ensure that it is withdrawn from the market, in accordance with the procedure in Article 8.

Article 19

Decisions in respect of refusal or restriction

1. 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 decisions 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 national law in force in the Member State in question and of the time limits to which such remedies are subject.

2. In the event of a decision as referred to in paragraph 1, the manufacturer, or his authorized representative established in the Community, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measure to be taken.

Article 20

Confidentiality

Without prejudice to the existing national provisions and practices on medical secrets, 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.

Article 21

Repeal and amendment of Directives

1. Directive 76/764/EEC is hereby repealed with effect from 1 January 1995.
2. In the title and Article 1 of Directive 84/539/EEC, the words 'human or' are deleted.

In Article 2 of Directive 84/539/EEC, the following subparagraph is added to paragraph 1:

'If the appliance is at the same time a medical device within the meaning of Directive.../.../EEC and if it satisfies the Essential Requirements laid down therein for that device, the device shall be deemed to be in conformity with the requirements of this Directive.'

3. Directive 90/385/EEC is hereby amended as follows:
 - 1) In Article 1(2) the following two subparagraphs are added:
 - (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 sub-paragraph does not apply to the person who, while not a manufacturer within the meaning of the first sub-paragraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;

- 2) In Article 9 the following paragraphs are added:

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.

8. Decisions taken by the notified bodies in accordance with Annexes II and III 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 five years.

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.'

3) The following Article 9a is inserted after Article 9;

Article 9a

1. Where a 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, it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures. These measures shall be adopted in accordance with the procedure referred to in Article 7(2) of Directive 93/.../EEC.

2. The Commission shall inform the Member States of the measures taken and, where appropriate, publish the relevant parts of these measures in the Official Journal of the European Communities.'

4) The following is added to Article 14:

'In the event of a decision as referred to in the previous paragraph the manufacturer, or his authorized representative established in the Community, 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.'

Article 22

Implementation, transitional provisions

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1994. They shall immediately inform the Commission thereof.

The Standing Committee referred to in Article 7 may assume its tasks from the date of notification¹ of this Directive. The Member States may take the measures referred to in Article 16 on notification of this Directive.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such a reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

¹This Directive was notified to the Member States on

Member States shall apply these provisions with effect from 1 January 1995.

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 take the necessary action to ensure that the notified bodies which are responsible pursuant to Article 11(1) to (5) for conformity assessment take account of any relevant information regarding the characteristics and performance of such devices, including in particular the results of any relevant tests and verification already carried out under pre-existing national law, regulations or administrative provisions in respect of such devices.

4. Member States shall accept the placing on the market and putting into service of devices which conform to the rules in force in their territory on 31 December 1994 during a period of five years following adoption of this Directive.

In the case of devices which have been subjected to EEC pattern approval in accordance with Directive 76/764/EEC, Member States shall accept their being placed on the market and put into service during the period up to 30 June 2004.

Article 23

This Directive is addressed to the Member States.

Done at Brussels,

For the Council

The President

