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databank. On the basis of this evaluation, the Commission shall, if appropriate, present proposals to the European Parliament and the Council or present draft measures in accordance with paragraph 3.

*Article 14b***Particular health monitoring measures**

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protection of health and safety and/or to ensure that public health requirements are observed, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited, restricted or subjected to particular requirements, it may take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

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

The Commission shall, whenever possible, consult the interested Parties and the Member States.

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

When appropriate, the necessary measures designed to amend non-essential elements of this Directive, relating to withdrawal from the market, prohibition of placing on the market and putting into service of a certain product or group of products or to restrictions or introduction of particular requirements in order for such products to be put on the market, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 7(4).

▼B*Article 15***Clinical investigation****▼M5**

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

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

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

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

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

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

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

7. The manufacturer or his authorised representative shall notify the competent authorities of the Member States concerned of the end of the clinical investigation, with a justification in case of early termination. In the case of early termination of the clinical investigation on safety grounds this notification shall be communicated to all Member States and the Commission. The manufacturer or his authorised representative shall keep the report referred to in Section 2.3.7 of Annex X at the disposal of the competent authorities.

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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 CE 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 Article 11 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.

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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 XI for the designation of bodies by the Member States shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).

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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

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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 ►**M5** ————— ◀, shall lay down, by common accord, the time limits for completion of the assessment and verification operations referred to in Annexes II to VI.

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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.

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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 where 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 Annex XI requirements.

▼B*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 CE 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 CE marking 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:

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

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- (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.

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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.

▼B*Article 19***Decision 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 ►**M5** ————— ◀, 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.

▼M5*Article 20***Confidentiality**

1. Without prejudice to the existing national provisions and practices on medical confidentiality, Member States shall ensure that all the Parties involved in the application of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks.

This does not affect the obligation of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

2. The following information shall not be treated as confidential:
- (a) information on the registration of persons responsible for placing devices on the market in accordance with Article 14;
- (b) information to users sent out by the manufacturer, authorised representative or distributor in relation to a measure according to Article 10(3);
- (c) information contained in certificates issued, modified, supplemented, suspended or withdrawn.

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3. The measures designed to amend non-essential elements of this Directive, *inter alia* by supplementing it, relating to determination of the conditions under which other information may be made publicly available, and in particular for Class IIb and Class III devices to any obligation for manufacturers to prepare and make available a summary of the information and data related to the device, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).

*Article 20a***Cooperation**

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

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

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

▼B*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, ‘human or’ is 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 93/42/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.

(*) OJ No L 169, 12.7.1993, p. 1.’

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 subparagraph

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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;’

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 93/42/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*.

(*) OJ No L 169, 12.7.1993, p. 1.’

4. Article 10 shall be amended as follows:

— the following subparagraph shall be added to paragraph 2:

‘Member States may however authorize manufacturers to start the clinical investigations in question before the expiry of the 60-day period, provided that the Ethical Committee concerned has delivered a favourable opinion with respect to the investigation programme in question.’,

— the following paragraph shall be inserted:

‘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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5. 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 notification ⁽¹⁾ 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.

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.

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4. Member States shall accept:

- devices which conform to the rules in force in their territory on 31 December 1994 being placed on the market during a period of five years following the adoption of this Directive, and
- the aforementioned devices being put into service until 30 June 2001 at the latest.

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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.

⁽¹⁾ This Directive was notified to the Member States on 29 June 1993.

▼B*ANNEX I***ESSENTIAL REQUIREMENTS****I. GENERAL REQUIREMENTS****▼M5**

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

This shall include:

- reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and
- consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

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2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- eliminate or reduce risks as far as possible (inherently safe design and construction),
- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted.

3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged 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 the manufacturer.
4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.
5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.
6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

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

▼B**II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION**

7. **Chemical, physical and biological properties**
 - 7.1. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. Particular attention must be paid to:

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- the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,
- the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device,

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

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- 7.2. The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.
- 7.3. The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.

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

For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004⁽¹⁾ on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.

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

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in

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

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order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device.

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

- 7.5. The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ⁽¹⁾.

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

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

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- 7.6. Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.

8. **Infection and microbial contamination**

- 8.1. The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.
- 8.2. Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.

Notified bodies shall retain information on the geographical origin of the animals.

Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other ► M5 transmissible ◀ agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.

- 8.3. Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.

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

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- 8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.
- 8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.
- 8.6. Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.
- 8.7. The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.
9. **Construction and environmental properties**
- 9.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.
- 9.2. Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:
- the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,
 - risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,
 - the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,
 - risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.
- 9.3. Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.
10. **Devices with a measuring function**
- 10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.
- 10.2. The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.
- 10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC ⁽¹⁾.
11. **Protection against radiation**
- 11.1. *General*
- 11.1.1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

⁽¹⁾ OJ No L 39, 15.2.1980, p. 40. Directive as last amended by Directive 89/617/EEC (OJ No L 357, 7.12.1989, p. 28).

▼B11.2. *Intended radiation*

- 11.2.1. Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.
- 11.2.2. Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.

11.3. *Unintended radiation*

- 11.3.1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.

11.4. *Instructions*

- 11.4.1. The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.

11.5. *Ionizing radiation*

- 11.5.1. Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.
- 11.5.2. Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.
- 11.5.3. Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.

12. **Requirements for medical devices connected to or equipped with an energy source**

- 12.1. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.

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

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- 12.2. Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.
- 12.3. Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.
- 12.4. Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.
- 12.5. Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.

▼B12.6. *Protection against electrical risks*

Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.

12.7. *Protection against mechanical and thermal risks*

12.7.1. Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.

12.7.2. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

12.7.3. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

12.7.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.

12.7.5. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.

12.8. *Protection against the risks posed to the patient by energy supplies or substances*

12.8.1. Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.

12.8.2. Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.

Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.

12.9. *The function of the controls and indicators must be clearly specified on the devices.*

Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

13. **Information supplied by the manufacturer****▼M5**

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

▼B

This information comprises the details on the label and the data in the instructions for use.

As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.

Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.

▼B

13.2. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.

13.3. *The label* must bear the following particulars:

▼M5

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

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

▼B

(c) where appropriate, the word 'STERILE';

(d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number;

(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;

▼M5

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

▼B

(g) if the device is custom-made, the words 'custom-made device';

(h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';

(i) any special storage and/or handling conditions;

(j) any special operating instructions;

(k) any warnings and/or precautions to take;

(l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;

(m) where applicable, method of sterilization;

▼M2

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

▼B

13.4. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.

13.5. Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.

13.6. Where appropriate, the instructions for use must contain the following particulars:

(a) the details referred to in Section 13.3, with the exception of (d) and (e);

(b) the performances referred to in Section 3 and any undesirable side-effects;

(c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;

▼B

- (d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;
- (e) where appropriate, information to avoid certain risks in connection with implantation of the device;
- (f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;
- (g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;
- (h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.

Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I.

▼M5

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

▼B

- (i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);
- (j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.

The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:

- (k) precautions to be taken in the event of changes in the performance of the device;
- (l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;
- (m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;
- (n) precautions to be taken against any special, unusual risks related to the disposal of the device;

▼M5

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

▼B

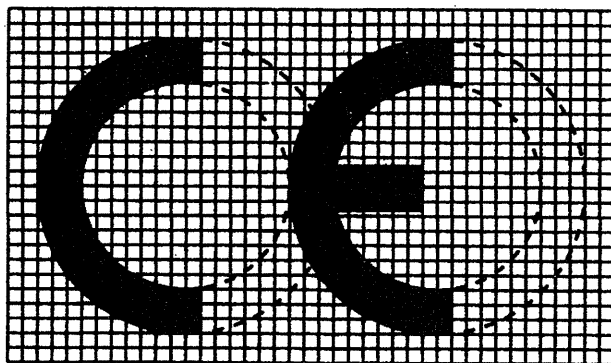
- (p) degree of accuracy claimed for devices with a measuring function;

▼M5

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

▼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.

本文書は専ら資料として使用されることを目的とするものであり、関連機関は内容についての責任を何ら負うものではない。

- ▶ **B** 医療機器に関する欧州理事会指令 93/42/EEC (1993年6月14日)
(1993年7月12日付 OJ L 169、p.1)

修正:

		Official Journal (官報)
	番号	ページ 日付
▶ <u>M1</u> 欧州議会・理事会指令 98/79/EC (1998年10月27日)	L 331	1 1998年12月7日
▶ <u>M2</u> 欧州議会・理事会指令 2000/70/EC (2000年11月16日)	L 313	22 2000年12月13日
▶ <u>M3</u> 欧州議会・理事会指令 2001/104/EC (2001年12月7日)	L 6	50 2002年1月10日
▶ <u>M4</u> 欧州議会・理事会規則(EC) No 1882/2003 (2003年9月29日)	L 284	1 2003年10月31日
▶ <u>M5</u> 欧州議会・理事会指令 2007/47/EC (2007年9月5日)	L 247	21 2007年9月21日

▼B

医療機器に関する欧州理事会指令 93/42/EEC (1993年6月14日)

欧州共同体理事会は

欧州経済共同体設立条約、特にその第100a条、

及び欧州委員会からの提案⁽¹⁾を考慮し、

欧州議会と共同で⁽²⁾、

経済社会評議会の意見を考慮し⁽³⁾、

以下を鑑みて、本指令を採択した。

措置は欧州域内市場に照らして講じられるべきである。欧州域内市場は商品、人、サービス、及び資本の自由な流通が保証されている内部国境のない地域である。

医療機器に関する安全性、健康保護、及び性能特性に関する内容及び範囲は、加盟国で施行されている法律、規則、及び行政規定によって異なる。医療機器の認可及び審査の手順は加盟国によって異なる。このような差異が欧州共同体内の貿易障壁となっている。

医療機器の使用に関する患者、使用者、及び該当する場合にはその他の者の安全性及び健康保護のための各国の規定は、医療機器の欧州域内市場内での自由な流通を保証するために統一するべきである。

これらの統一された規定は、医療機器に直接的又は間接的に関連する公衆衛生及び健康保険スキームの財源を管理するために加盟国によって採択された措置と区別されなくてはならない。従って、これらの規定は、欧州共同体法が遵守されている限りにおいて、加盟国の上述の措置を実施する能力に影響しない。

(1)1991年9月12日付 OJ (欧州官報) No C 237、及び1992年9月28日付 OJ No C 251、p. 40。

(2)1993年5月31日付 OJ No C 150、及び1993年6月28日付 OJ No C 176。

(3)1992年3月30日付 OJ No C 79、p. 1。

医療機器は患者、使用者、及び第三者に高水準の保護を提供するものであり、製造者が設定する性能レベルを達成しているべきである。従って、加盟国における保護の水準の維持又は改善が本指令の基本目的の一つである。

一部の医療機器は、特許を取得している医薬製造物に関する法律、規則、又は行政措置によって定められている規則の近似化に関する理事会指令 65/65/EEC (1965年1月26日)⁽⁴⁾の意味の範囲内の医薬製造物の投与を目的とするものである。このような場合、医療機器の販売には一般規則として本指令が適用され、医薬製造物の販売には指令 65/65/EEC が適用される。しかしこのような機器が、機器及び医薬製造物によって単一のユニットが形成されるもので、この組合せでのみ使用することが意図されており、再利用不可能なように販売されている場合には、その単一のユニットの製品には指令 65/65/EEC が適用される。上述の機器、及び特に個別に使用された場合に指令 65/65/EEC の意味の範囲内で医薬製造物と考慮される可能性のある物質が組み入れられている医療機器とを区別しなければならない。このような場合には、医療機器に組み入れられている医薬製造物が医療機器の作用への付随的な作用により人体に作用するとされるものである場合、当該機器の販売は本指令に準拠する。この状況において、医薬製造物の安全性、品質、及び有用性は、市販される医薬品の試験に関する分析、薬理毒性、臨床に関する基準及び手順に関する加盟国の法律の近似化にかかわる理事会指令 75/318/EEC(1975年5月20日)⁽⁵⁾に規定されている適切な方法による類推によって検証されなければならない。

本指令の附属書に規定する基本要件及びリスクの「最小化」又は「抑制」に関する要件などのその他のあらゆる要件は、設計当時の技術及び慣習を考慮に入れ、高水準の健康保護及び安全性と両立する技術的及び経済的考慮点を考慮に入れるように解釈及び適用されなければならない。

技術の統一及び標準化の新しいアプローチに関する 1985年5月7日の理事会決議で定められた原則⁽⁶⁾に従い、医療機器の設計及び製造に関する規則は基本要件を満たすために必要な規定に限定されなければならない。このような要件は必要不可欠であるため、これは対応する各国の規定と置き換えられるべきであ

⁽⁴⁾1965年6月9日付 OJ No 22、p. 369/65。指令 92/27/EEC (1992年4月30日付 OJ No L 113、p. 8)により最終改訂。

⁽⁵⁾1975年6月9日付 OJ No L 147、p. 1。指令 91/507/EEC (1991年9月26日付 OJ No L 270、p. 32)により最終改訂。

⁽⁶⁾1985年6月4日付 OJ No C 136、p. 1。

る。基本要件は設計当時の技術と慣習、及び高水準の健康保護及び安全性と両立する技術的及び経済的考慮点を考慮に入れるよう慎重に適用されるべきである。

能動植込み型医療機器に関する加盟国の法律の近似化に関する理事会指令 90/385/EEC (1990年6月20日)⁽⁷⁾は、この新しいアプローチの医療機器分野への初めての適用例である。全ての医療機器に適用される一様な欧州共同体規則のために、本指令は主に指令 90/385/EEC の規定に基づくものである。同じ理由から、指令 90/385/EEC は本指令で制定した一般規定を加えるよう修正されるべきである。

電磁適合性の側面は医療機器の安全性の重要部分となっている。本指令には電磁適合性に関する加盟国の法律の近似化に関する理事会指令 89/336/EEC (1989年5月3日)⁽⁸⁾に関連する電磁適合性に関する特別な規則が含まれるべきである。

本指令には電離放射線を放出する機器の設計及び製造に関する要件が含まれるべきである。本指令は、電離放射線の危険から公衆及び労働者の健康を守るための基本的な安全性基準を定めている指令を修正する理事会指令 80/836/Euratom (1980年7月15日)⁽⁹⁾によって要求されている承認に影響を及ぼさず、医学検査又は治療を受ける人を放射線から保護するための基本的方法を定めた理事会指令 84/466/Euratom (1984年9月3日)⁽¹⁰⁾の適用にも影響を及ぼさない。職場での労働者の安全性及び健康の改善を促進させるための対策の導入に関する理事会指令 89/391/EEC (1989年6月12日)⁽¹¹⁾及び同じ主題に関する特定の指令は継続して適用されるべきである。

基本要件への適合性を立証し、適合性を検証可能とするため、医療機器の設計、製造、及び包装に関連するリスクを抑制するための欧州整合規格を制定することが望ましい。このような欧州整合規格は民間の法律機関が作成するもので、強制力のないものとされるべきである。このため、欧州標準化委員会(CEN)及び欧州電気技術標準化委員会(CENELEC)は、1984年11月13日に署名した欧州委員会とこれら 2 機関の協力に関する一般ガイドラインに従って、整合規格の採

(7)1990年7月20日付 OJ No L 189、p. 17。

(8)1989年5月23日付 OJ No L 139、p. 19。指令 92/31/EEC (1992年5月12日付 OJ No. L 126、p. 11)により最終改訂。

(9)1980年9月17日付 OJ No L 246、p. 1。指令 84/467/Euratom (1984年10月5日付 OJ No L 265、p. 4)により最終改訂。

(10)1984年10月5日付 OJ No L 265、p. 1。

(11)1989年6月29日付 OJ No L 183、p. 1。