COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 23 August 1991

Proposal for a

COUNCIL DIRECTIVE

concerning medical devices

(presented by the Commission)

EXPLANATORY MEMORANDUM

I. GENERAL FRAMEWORK

This proposal for a directive has been prepared in the context of the White Paper on completing the internal market, the work programme of which provides for harmonization of the laws relating to electro-medical equipment.

In this context, the Council adopted a first directive relating to active implantable medical devices (Directive 90/385/EEC) on 20 June 1990. With the adoption of this directive, a preponderant part of the field of medical devices will be covered by harmonized laws. However, medical devices intended for *in vitro* diagnosis are not included in the scope of this proposal. These products will be dealt with, in view of their particular nature, in a specific directive.

Before starting on the preparation of its proposal, the Commission examined the regulations relating to the medical devices sector. The results of this examination confirmed that there are considerable differences between the Member States as regards both the technical design and production requirements and the administrative procedures for the examination, testing, inspection and authorization for marketing, and the putting into service and after-sales surveillance of medical devices.

The current legislative situation in the Member States is characterized by a marked lack of uniformity if the various national laws are compared with regard to their scope and the kind of risks covered. A large number of specific laws cover certain groups of products such as electro-medical equipment, disposable products, equipment for the disabled, sterile products, and even specific products. In several Member States, a range of medical devices (in particular in the field of sterile and disposable products) are covered, in the absence of specific laws, by the regulations on medicinal products. The fact that medical equipment, which as a general rule acts physically, is sometimes treated the same as medicinal products, which act pharmacologically, has led in several cases to technical barriers.

With the regard to the means of control used to ensure the safety and health protection of patients and users, two different approaches were found in the Community. A large number of the Member States apply systems based on the inspection of products before they are placed on the market by means of type-examinations or approval systems, while others ask companies to apply good manufacturing practices. Where the devices are subject to the rules on medicinal products, both product certification and authorization procedures for companies apply.

The information obtained pursuant to Directive 83/189/EEC laying down an information procedure in the field of technical regulations confirms the lack of uniformity in the legislative approach taken with regard to medical devices. Between 1988 and 1990, some 25 sets of draft national regulations, most of them relating to specific products, were notified to the Commission.

Lastly, it should be said that some of the Member States are aware of the unsatisfactory situation and have indicated their desire to establish an overall legal framework for the medical devices field.

In view of the differences in approach, which by their nature are incompatible with a single Community market in medical devices, it is essential to set up a Community system of laws based on Article 100a of the EEC Treaty to abolish and prevent technical barriers to trade.

The aim of this directive, therefore, is to ensure the safety and health protection of patients and users by means of a uniform sectoral approach and to create an appropriate, suitable framework for the technological development of the products concerned.

The medical devices sector is a large market: world consumption of these products in 1990 has been put at ECU 54.1 billion, including ECU 23.1 billion in the USA a(1 ECU = 1.2 US$) and ECU 15.0 billion in the Community (source: Health Industry Manufacturers Association (HIMA)). The Community share of world production has been calculated to be ECU 16.1 billion (USA: 25.7 - Japan: 8.0). Between 1986 and 1989, the annual average growth in consumption was 9.5% (USA: 9.9% - Japan: 8.6%). The number of jobs in this branch of industry within the Community totalled over 200 000 in 1990.

In view of the rapid speed of innovation in this sector, Community legislation will provide an appropriate framework which will help to maintain and to promote this favourable development.

The proposal for a directive has been designed and structured, as regards technical requirements, in the light of the Council Resolution of 7 May 1985 on a new approach to technical harmonization and standardization The legislators already applied the principles set out in the abovementioned Resolution with the adoption of Council Directive 90/385/EEC of 20 June 1990 relating to active implantable medical devices. This proposal therefore includes what has been achieved with that Directive and transposes it to the medical devices which it covers.

The implementation of the concept of reference to standards will be facilitated by the fact that some of the harmonized European standards, in particular those of a horizontal nature, will already be available from the application of the Directive relating to active implantable medical devices. Furthermore, important work on the establishment of a sectoral system of harmonized standards has already been started by CEN/CENELEC.

The part of the directive relating to procedures for the assessment of conformity is based on the modular approach set out in Council Decision 90/683/EEC of 13 December 1990

The approach followed with regard to the assessment of conformity enables a distinction to be made with regard to verifications carried out by a third party according to the nature of the potential risk inherent in medical devices. For this reason and in view of the diversity of products concerned, the devices covered by the directive have been divided into four classes for the purpose of assessment procedures.

The intervention of the certification bodies (notified bodies) has been graded. For devices in Class I, conformity is established as a general rule under the responsibility of the manufacturer alone. Class IIa devices require, in view of the risks more closely associated with manufacture, the intervention of a notified body with regard to the manufacture stage. For devices in Classes IIb and III, on the other hand, verification by a notified body is necessary with regard to design and the manufacturing stage. Furthermore, Class III devices which are critical devices should, as a general rule, undergo a clinical evaluation under the responsibility of the manufacturer. The conformity of their design must be explicitly certified by a notified body before they are placed on the market.

(1) OJ No C 136, 4.6.1985, p. 1.
(2) OJ No L 189, 20.7.1990, p. 17.
(3) OJ No L 380, 31.12.1990, p. 13.

II. CONTENTS OF THE PROPOSAL

1. Article 1 - Scope

Several definitions, in particular those of a "medical device", a "custom-made device" and a "device intended for clinical investigation" have been taken from the Directive relating to active implantable medical devices. Since the scope of this proposal is broader than that of the abovementioned Directive, a few slight amendments have therefore been made.

The term "medical device" means products the function of which is solely or principally medical. A series of products whose function is not essentially medical are therefore excluded from the scope, even if these products may be used to prevent disease or alleviate a handicap, e.g. cosmetic products, multiple-use data-processing equipment.

The medical function of a medical device may be fulfilled either by means of a product used on its own or as the result of the combination of several products, e.g. disposable tubings combined with an infusion pump.

The criterion for the distinction between a medical device and a medicinal product is the principal action produced. A product which achieves its principal action by pharmacological, immunological or metabolic means is not considered to be a medical device. However, a medical device may include a medicinal substance as an integral part in order to increase its effectiveness, e.g. a heparin-coated catheter.

Where the action produced by the presence of the medicinal substance is secondary to the principal action of the device, the conformity assessment procedure for authorizing the placing of the product concerned on the market is covered by this proposal for a directive. As far as safety aspects concerning the presence of the substance are concerned, the verifications required are carried out, where appropriate, by analogy to the methods contained in Directive 75/318/EEC.

On the other hand, where a device is intended to administer a medicinal product and therefore constitutes a container for that product, e.g. a pre-filled syringe, the aspects relating to the safety of the device are covered by this proposal, while the placing of the medicinal product on the market is subject to the Community legislation relating to medicinal products (see Article 1, para. 3).

The key legal definitions include definitions of "placing on the market" and the "manufacturer". The "placing on the market" means the physical transfer of a medical device from the manufacturer or a person authorized by him to the distributor or user. Placing on the market must not be confused with the right, under the directive, to market medical devices in the European Community. The definition of the manufacturer is useful in order to be able to determine the natural or legal persons subject in particular to the conformity assessment procedures (Article 10).

The scope of this proposal includes medical devices which emit ionizing radiation. It therefore specifies the requirements relating to the design and manufacture of the equipment concerned and the conformity assessment procedures. The directive does not, however, affect the authorization required under Directive 80/836/Euratom for the putting into service and use of such equipment.

2. Articles 2 and 3

These are conventional Articles based on the new approach relating to placing on the market, putting into service and essential requirements.

3. Article 4 - Free movement, devices intended for special purposes

In addition to the conventional clause concerning free movement, this Article refers to devices intended for special purposes, i.e. devices intended for clinical investigation and custom-made devices.

Devices intended for clinical investigation are made available to medical practitioners when total compliance with the essential requirements still has to be established so that the device can undergo an assessment of conformity procedure. The carrying out of clinical investigations specifically makes it possible to confirm conformity with the relevant essential requirements. Such devices therefore do not bear the CE mark.

Custom-made devices are made in accordance with the prescription of a medical specialist or any other authorized person giving the specific design characteristics of the device concerned. Compliance with the requirements of the directive is therefore established under the joint responsibility of the manufacturer and the person issuing the prescription and this is why such devices do not have to bear the CE mark.

4. Article 5 - Reference to standards

The reference to harmonized standards clause is based on the Council Resolution of 7 May 1985.

By means of the reference to certain monographs of the European Pharmacopoeia in paragraph 2, the Community is discharging the obligations incumbent on the Member States pursuant to the Convention of 22 July 1964 on the preparation of a European Pharmacopoeia.

In the field of the medical devices covered by this proposal, the European Pharmacopoeia has prepared several monographs relating in particular to sutures and the interaction between certain materials used for devices and medicinal products. Subject to Article 5, paragraph 2, these monographs will have the same status, under this proposal, as harmonized standards. The application of the monographs will therefore remain voluntary.

The Commission has proposed to the CEN and the European Pharmacopoeia the conclusion of a memorandum of understanding to determine the respective fields of activity and to establish collaboration in areas of common interest.

5. Articles 6 and 7 - Committees

Regardless of the conventional role of the Committee set up under Directive 83/189/EEC (cf. Article 5(3)), the field of activity of the Advisory Committee set up under Directive 90/385/EEC has been extended to the sector covered by the proposal. Any matter relating to the implementation and practical application of the Directive may be brought before this Committee.

With regard to the classification of medical devices into four classes of products (see Articles 8 and 12), regulatory measures have to be laid down at Community level for the products concerned. In view of the nature of these measures and the consequences as regards the level of intervention of third parties, the measures should be adopted in accordance with the "Regulatory Committee" procedure (variant IIIa of Council Decision 87/373/EEC of 13 July 1987 laying down the procedures for the exercise of implementing powers conferred on the Commission).

6. Article 8 - Safeguard clause

This Article is based on the Council Resolution of 7 May 1985 concerning the new approach.

7. Articles 9 and 13 - Classification

Medical devices are divided into four product classes in order to be able to decide on the appropriate level of intervention by the notified bodies. The classification rules set out in Annex 9 enable manufacturers to classify their products according to the relevant class. Where there is doubt, manufacturers may contact the competent authorities which, for their part, may, if necessary, initiate the Community decision-making process.

Decisions may have to be taken with regard to the classification of medical devices in particular where:

- the classification rules and the Commission guidelines do not enable a straightforward classification to be made;
- the experience obtained with specific families of products justifies a reclassification by way of derogation from the classification rules;
- the classification rules need to be adjusted in the light of technical development and/or experience with given devices.

8. Article 10 - Information on incidents occurring following placing of devices on the market

This Article sets up a Community warning system regarding incidents occurring with devices already placed on the market. This system will enable the Member States to take appropriate measures early on where an incident suggests that, because of a design or manufacturing fault, a device may seriously damage the health of patients or users.

The obligations on manufacturers to notify certain incidents are set out in Annex 2, point 3.1, Annex 4, point 3, Annex 5, point 3.1, and Annex 6, point 3.1. Each Member State must set up a central unit to record and evaluate the reports obtained. Where measures have to be taken by the national authorities, the Member State concerned must inform the other Member States and the Commission.

9. Article 11, Annexes 2 to 7 - Conformity assessment procedures

Suitable conformity assessment procedures have been selected from among those adopted in Council Decision 90/683/EEC of 13 December 1990 and supplemented according to sectoral requirements. The minor additions made refer in particular to the documentation required, the safety of combined devices, sterilization procedures and clinical data. The following procedures apply to the four classes of devices:

- Class I — the manufacturer alone is responsible for the assessment of conformity (module A of Council Decision 90/683/EEC)

- Class IIa — the manufacturer himself is responsible for assessing the product design. The intervention of a notified body is required at the production stage (module A combined with either modules D, E or F). Furthermore, the manufacturer may opt for full quality assurance (module H), although the procedure specified in that module is more restrictive than those mentioned above.

- Class IIb the design and manufacture of the product must be referred to a notified body. The manufacturer may follow either the full quality assurance procedure (module H) or submit a prototype for type-examination (module B). In the case of the latter, the manufacturer must also apply one of the procedures referred to in modules D, E or F.

- Class III the procedures are broadly the same as those set out for Class IIb. However, if full quality assurance is applied (module H) the file relating to the product design must be examined. Furthermore, regardless of the procedure followed the design file must as a general rule include an assessment of conformity based on clinical data (see Annex 10, point 1.1).

The manufacturers' choice of several procedures will make it possible to select the most appropriate procedure taking account in particular of the pre-existing regulatory system and the nature and size of the company.

10. Article 12 - Assembly and sterilization

This Article refers to assembly and sterilization activities carried out commercially. It applies to devices already bearing the CE mark. The person who carries out the activities concerned is not considered to be the manufacturer as legally defined where the activities are carried out in accordance with the manufacturer's instructions.

If, however, assembly and sterilization go beyond the limits laid down by the manufacturer of the devices, they are specific manufacturing activities which are then subject to the procedures set out in Article 10.

The procedures referred to in Article 11 apply regardless of the classification of the device.

11. Article 14 - Registration of persons responsible for placing devices on the market

This Article applies to devices which are not subject to inspection by a notified body before being placed on the market. These are the Class I devices and custom-made devices. For these devices, the manufacturer or person(s) responsible for placing them on the market must inform the competent authorities of the address of their registered place of business and the category of devices concerned. This notification enables the Member States to have better control of the devices in question which are marketed in their territory and, if necessary, to take appropriate measures.

12. Article 15 - Clinical investigation

Clinical investigations may be necessary in order to confirm that a device fully complies with the essential requirements. The competent authorities of each Member State in which the investigations are carried out must be able to intervene, if necessary, to protect the health of patients and public order. Article 14, paragraph 2, lays down a tacit approval procedure for implantable and other devices in Class III.

The right of intervention of the competent authorities is centred on considerations of public health and public order. For this reason, intervention by the authorities does not include a preliminary evaluation of other aspects which are the subject of the conformity assessment procedures. The role of an ethics committee in this context is to evaluate the acceptability of the plan of investigations from the viewpoint of patient health and ethical considerations.

The competent authorities are not bound by the opinion expressed by an ethics committee. However, such an opinion may make it easier for them to examine the file.

13. Articles 16 to 19 - Notified bodies, EC mark

These are Articles typical of the new approach directives.

14. Article 20 - Confidentiality

The observance of confidentiality is essential for the protection of specific data and because of the economic impact of the procedures for the parties concerned.

15. Article 21 - Guidelines

The documents referred to in the guidelines are based on the practice followed with regard to medicinal products as set out in Directive 89/341/EEC. The guidelines may provide useful information for the application of the directive, although they do not themselves have any legal force. They will cover aspects that are not dealt with in harmonized standards.

16. Article 22 - Repeal and amendment of Directives

Directive 76/764/EEC covers mercury-in-glass thermometers. It is an optional Directive. The products and features concerned are covered by the scope of this directive.

The amendment of Directive 84/539/EEC restricts its scope to electro-medical equipment used in veterinary medicine. Equipment used in human medicine is covered by this proposal.

The purpose of amending Directive 90/385/EEC is to add to that Directive the general provisions in this proposal so as to apply them to all medical devices. The existing provisions of Directive 90/385/EEC are not affected. The amendments will therefore not have any effect on the transposition of the abovementioned Directive.

17. Article 23 - Implementation, transitional provisions

Article 23, paragraph 4, provides for the optional application of the directive up to June 1997 to medical devices which must undergo certification by a third party. This period is necessary in order to avoid the additional certification workload which would arise with a shorter transitional period. To avoid the unnecessary repetition of tests and verifications, Article 23, paragraph 3, states that the notified bodies must take account of the results of tests and verifications already carried out under pre-existing national regulations.

18. Annex 1 - Essential requirements

This Annex is largely based on Directive 90/385/EEC.

19. Annex 8 - Procedures for devices for special purposes

The procedures and statements referred to in this Annex apply to custom-made devices and devices intended for clinical investigations. They are based on the solution adopted in the Council Directive relating to active implantable medical devices.

20. Annex 9 - Classification rules

This Annex lays down the rules for the classification of medical devices for the application of the conformity assessment procedures. The concept of classification is essentially based on the vulnerability of the human body following the use of a medical device. It also takes account of the consequences of functional defects in medical devices. The basic criteria for the classification rules are as follows:

- contact or interaction of a device with the human body;
- contact with injured skin;
- the invasive nature of a device with regard to the orifices of the human body or of a surgical device;
- implantation of a device in the body;
- contact with vital organs (heart, central nervous system);
- the delivery of energy or substances into or onto the body.

On the above basis, devices which do not enter into contact or interact with the body are generally classified in Class I.

Devices which are invasive or implantable or which interact with the body are largely (apart from certain particular aspects) in Class IIa or IIb.

A small number of devices concerning in particular the functions of vital organs are in Class III. Devices which are activated by an energy source and which in principle should be in Class III are already covered by the Directive relating to active implantable medical devices. The provisions of that Directive correspond to those laid down for Class III devices.

21. Annex 10 - Clinical evaluation

Annex 10 has been adopted from the Directive relating to active implantable medical devices. It specifies the subject of the clinical data and the procedures to be followed for obtaining the data. Clinical evaluation is carried out under the manufacturer's responsibility. It may be a feature required in the technical documentation referred to in the conformity assessment procedures. The harmonized provisions contained in this Annex will avoid repetition of the same clinical investigations in more than one Member State.

22. Annexes 11 and 12 - Minimum criteria for the notified bodies, EC mark

These are Annexes typical of the new approach directives.

Proposal for a

COUNCIL DIRECTIVE

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 Commission(1),

In cooperation with the European Parliament(2),

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

Whereas measures should be adopted for the progressive establishment 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;

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(1) OJ No C
(2) OJ No C
(3) OJ No C

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;

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 products[4], as last amended by Directive 89/381/EEC[5]; whereas, in such cases the placing of the medicinal product on the market is 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; whereas, in such cases, if the substances are incorporated in the medical devices to help them operate, the placing of the devices on the market is governed by this Directive; whereas, in this context, in the event of the bioavailability of such substances, 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 products[6], as last amended by Directive 89/341/EEC[7],

(4) OJ No L 22, 9.2.1965, p. 369/65.
(5) OJ No L 181, 28.6.1989, p. 44.
(6) OJ No L 147, 9.6.1975, p. 1.
(7) OJ No L 142, 25.5.1989, p. 11.

Whereas, in accordance with the principles set out in the Council Resolution of 7 May 1985 concerning a new approach to technical harmonization and standardization[8], 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;

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 devices[9] 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 electromagmetic compatibility[10], as amended by Directive 91/263/EEC[11]

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 radiation[12], as amended by Directive 84/467/Euratom[13], nor application of Council Directive 84/446/Euratom of 3 September 1984 laying down basic measures for

(8) OJ No C 136, 4.6.1985, p. 1.
(9) OJ No L 189, 20.7.1990, p. 17.
(10) OJ No L 139, 23.5.1989, p. 19.
(11) OJ No L 128, 23.5.1991, p. 1.
(12) OJ No L 246, 17.9.1980, p. 1.
(13) OJ No L 265, 5.10.1984, p. 4.

the radiation protection of persons undergoing medical examination or treatment[14]; whereas Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work[15] and the specific directives on the same subject should continue to apply;

Whereas this Directive does not affect Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[16], as last amended by Directive 91/184/EEC[17]; whereas the assessment whether a product is subject to the abovementioned Directive or to this Directive must take account, in particular, of the intended purpose of the product in question and of the place of application;

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 cooperation 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 regulations[18], as last amended by Commission Decision 90/230/EEC[19], 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

(14) OJ No L 265, 5.10.1984, p. 1.
(15) OJ No L 183, 29.6.1989, p. 1.
(16) OJ No L 262, 27.9.1976, p. 169.
(17) OJ No L 91, 12.4.1991, p. 59.
(18) OJ No L 109, 26.4.1983, p. 8.
(19) OJ No L 128, 18.5.1990, p. 15.

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/EEC[20]; 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 directives[21], the Council has laid down harmonized conformity assessment procedures; whereas the application of these modules to medical devices enables the responsibility of manufacturers and certification 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 certification body (notified body) should be compulsory at the production stage; whereas, for devices falling within Classes IIb and III which, in case of malfunction, 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;

(20) OJ No L 197, 18.7.1987, p. 33.
(21) OJ No L 380, 31.12.1990, p. 13.

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;

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 level[22], 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 III(a), as provided for in Decision 87/373/EEC;

Whereas it is appropriate that the Member States, as provided for by Article 100a of the Treaty, may take temporary measures to limit or prohibit the placing on the market and the use of medical devices in cases where they present a particular risk to the health of persons, provided that the measures are subject to a Community control procedure;

(22) OJ No C 185, 22.7.1989, p.8.

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 application of some provisions of this Directive must be facilitated by means of guidelines published by the Commission;

Whereas the protection of health and the associated controls may be made more effective by means of a medical device vigilance system 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 thermometers(23), as last amended by Directive 84/414/EEC(24); 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 medicine(25) must be amended,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Definitions, scope

1. This Directive shall apply to medical devices. It also covers the accessories to which the provisions for medical devices apply.

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

(23) OJ No L 262, 27.9.1976, p. 139.
(24) OJ No L 228, 25.8.1984, p. 25.
(25) OJ No L 300, 19.11.1984, p. 179.

(a) "medical device" (hereinafter referred to as "devices") means any instrument, apparatus, appliance, material or other article, including software, whether used alone or in combination, intended by the manufacturer to be used on human beings solely or principally for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap,

- investigation, replacement or modification of the anatomy or of a physiological process,

- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

(b) "accessory" means an article which, while not a device, is required, according to the intended purpose attributed to it by the manufacturer, to enable a device to be used as specified.

(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 solely or principally *in vitro* for the examination of substances derived from the human body with a view to providing information for the detection, diagnosis, control or treatment of a physiological state, of a state of health or disease, or of a congenital abnormality.

(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 to be used only for an individual named 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 point 2.1 of Annex 10 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 specialist.

(f) "implantable device" means any device which is intended:

- to be totally or partially introduced into the human body or a natural orifice or

- to replace an epithelial surface or the surface of the eye

by surgical intervention, which is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention.

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

The natural or legal person who assembles, packages, processes 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 on his own behalf is also considered to be a manufacturer. 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.

(h) "intended purpose" means the use for which the device is intended and for which it is suited according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

(i) "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.

(j) "putting into service" means the stage when a device is ready for use for the first time on the Community market for its intended purpose.

(k) "bioavailability" means the release of a substance into or onto the human body in such a way that the interaction with the body can reasonably be detected.

3. Where a device is intended to administer a substance defined as a medicinal product within the meaning Article 1 of Directive 65/65/EEC, that substance shall be subject to the marketing authorization system provided for in that Directive.

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, that device must be assessed and authorized in accordance with this Directive.

5. This Directive does not apply to:

(a) devices used for *in vitro* diagnosis,

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

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

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

8. This Directive does not affect the application of Directive 76/768/EEC. The assessment whether a product is subject to the abovementioned Directive or to this Directive shall take account, in particular, of the intended purpose of the product in question and of the place of application.

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.

Article 3

Essential requirements

The devices must meet the essential requirements set out in Annex 1 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 EC mark.

2. Member States shall not create any obstacles to:

   - devices intended for clinical investigation being made available to medical specialists or authorized persons for that purpose if they meet the conditions laid down in Article 15 and in Annex 8.

- 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 8; Class IIa, IIb and III devices shall be accompanied by the statement referred to in Annex 8.

These devices shall not bear the EC mark.

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 referred to in points 13.3 and 13.6 of Annex 1 to be in their national language(s) when a device reaches the final user, regardless of whether it is for professional or other use.

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 provisions of 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 the national standards which transpose the abovementioned harmonized standards into national law.

2. For the purposes of this Directive, reference to harmonized standards also includes the monographs of the European Pharmacopoeia on surgical sutures and on interaction between medicinal products and materials used as containers for devices, the references of which have been published in the Official Journal of the European Communities.

3. Where the Commission, whether on its own initiative or at the request of one of the Member States, 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 implemention of this Directive.

Article 8

Safeguard clause

1. Where a Member State ascertains that the devices, 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 non-compliance 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, in so far it is claimed that the standards have been applied;

(c) shortcomings in the standards themselves.

These measures are applicable until the entry into force of the act provided for in paragraph 2.

2. The measures adopted under paragraph 1 shall be confirmed and extended, possibly amended, to the whole Community or repealed by an act of the Commission.

However, where the measures were adopted under paragraph 1 on the ground of a shortcoming in the standards provided for in Article 5, the procedure laid down in Article 6(2) is applicable.

3. Where a non-complying device bears the EC mark, 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 the classification rules set out in Annex 9.

2. Where there is doubt over the classification resulting from application of the rules contained in Annex 9, the manufacturer or his authorized representative established in the Community may ask the competent authorities to take a decision. In the event of a dispute between the manufacturer and the notified body concerned defined in Article 16 resulting from the application of the abovementioned rules, the latter shall refer the matter to the competent authorities who will reach a decision.

3. The classification rules set out in Annex 9 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 IIa, IIb or III device is recorded and evaluated in a centralized manner:

   (a) any deterioration in the characteristics and/or performance of a device, as well as any inaccuracies in the labelling or the instruction leaflet 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 connected with the device leading to systematic recall of devices of the same type by the manufacturer.

2. Where a Member State obliges 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.

4. The Commission shall adopt the necessary measures concerning the functioning of the information system referred to in paragraphs 1, 2 and 3 and the presentation of information.

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 EC mark, either:

   (a) follow the procedure relating to the EC declaration of conformity set out in Annex 2 (full quality guarantee), or

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

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

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

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 EC mark, follow the procedure relating to the EC declaration of conformity set out in Annex 7, coupled with either:

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

(b) the procedure relating to the EC declaration of conformity set out in Annex 5 (production quality guarantee), or

(c) the procedure relating to the EC declaration of conformity set out in Annex 6 (product quality guarantee).

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 EC mark, either:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex 2 (full quality guarantee); in this case, point 4 of Annex 2 is not applicable; or

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

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

(ii) the procedure relating to the EC declaration of conformity set out in Annex 5 (production quality guarantee), or

(iii) the procedure relating to the EC declaration of conformity set out in Annex 6 (product quality guarantee).

4. In the case of devices falling within Class I, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall follow the procedure referred to in Annex 7 and draw up the EC declaration of conformity required before placing the device on the market.

5. In the case of custom-made devices, the manufacturer shall follow the procedure referred to in Annex 8 and draw up the statement set out in that Annex before placing each device on the market.

6. 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.

7. The manufacturer may instruct his authorized representative established in the Community to initiate the procedures provided for in Annexes 3, 4, 7 and 8.

8. 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.

9. Decisions taken by the notified bodies in accordance with Annexes 2 and 3 shall be valid for a maximum of five years and may be extended on application for further periods of five years.

10. The records and correspondence relating to the procedures referred to in paragraphs 1 to 5 shall be in an official language of the Member State in which the procedures are carried out or in a language acceptable to the notified body.

Article 12

Assembly and sterilization

1. Any natural or legal person who assembles devices bearing the EC mark for their intended purpose and within the limits of use specified by their manufacturers with regard to their compatibility with other devices in order to put them on the market in the form of a system, kit or operation pack shall draw up a declaration in which he states that:

(a) he has verified the mutual compatibility of the devices which make up the system, kit or operation pack in accordance with the manufacturers' instructions and that assembly has been carried out in accordance with these instructions;

(b) the system, kit or operation pack has, where applicable, been packaged in accordance with the manufacturers' instructions or the limits applicable to the various devices;

(c) all of the activities referred to in (a) and (b) are subjected to appropriate methods of control and inspection.

Any such system, kit or operation pack shall not bear any additional EC mark. It shall be accompanied by the information referred to in point 13 of Annex 1 which includes, where appropriate, the information supplied by the manufacturers of the devices which have been assembled.

2. Any natural or legal person who, in the framework of an activity referred to paragraph 1, sterilizes devices bearing the EC mark, shall, at his choice, follow one of the procedures referred to in Annex 4 or 5. The application of the abovementioned Annexes and the intervention of the notified body are limited to the aspects of the procedure relating to the obtaining of sterility. The person shall draw up a declaration stating that sterilization has been carried out in accordance with the manufacturer's instructions.

3. This Article does not apply if one of the devices concerned does not bear the EC mark or if the EC mark for one of the devices has been affixed for a different intended purpose.

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 9 requires a decision with regard to the classification of a given device or family of devices, or

(b) a given device or family of devices should be classified, by way of derogation from the provisions of Annex 9, 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. Where appropriate, 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, on his own behalf, places devices on the market in accordance with the procedures referred to in Article 11(4) and (5) 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 category of devices concerned.

2. Where a manufacturer who places devices referred to in paragraph 1 on the market on his own behalf does not have a registered place of business in a Member State, he shall designate the person(s) responsible for marketing them and 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 falling within Classes I, IIa and IIb which are intended for clinical investigations, the manufacturer, or his authorized representative established in the Community, shall follow the procedure referred to in Annex 8 and keep the statement concerned at the disposal of the competent authorities.

2. In the case of devices falling within Class III and implantable devices falling within Classes IIa or IIb intended for clinical investigations, the manufacturer, or his authorized representative established in the Community, shall follow the procedure referred to in Annex 8 and, at least 45 days before the commencement of the investigations, submit the statement referred to in the abovementioned Annex to the competent authorities of the Member State in which the investigations are to be conducted.

The manufacturer may commence the relevant clinical investigations at the end of a period of 45 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public order.

3. The clinical investigations must be conducted in conformity with the provisions of Annex 10. The provisions of Annex 10 shall be adjusted in accordance with the procedure laid down in Article 7(2).

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

5. The manufacturer or his authorized representative established in the Community shall keep the report referred to in point 2.3.7 of Annex 10 at the disposal of the competent authorities.

6. 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 mark 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 10 remain applicable.

Article 16

Notified bodies

1. The Member States shall notify the other Member States and the Commission 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. In this Directive, these bodies are referred to as "notified bodies".

The Commission shall allocate an identification number to these bodies and inform them and the Member States of it. It 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 minimum criteria set out in Annex 11 for the designation of bodies. Bodies that meet the criteria laid down in the relevant harmonized standards shall be presumed to meet the relevant minimum 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 2 to 6.

Article 17

EC 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 mark of conformity when they are placed on the market.

2. The EC mark of conformity, as shown in Annex 12, must appear in a visible, legible and indelible form on the device, where practicable and appropriate, and/or on the sales packaging and the instruction leaflet.

It shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes 2, 4, 5 and 6 and the last two digits of the year in which the mark was affixed.

3. In the event of a significant change in the intended purpose of a device, the EC mark may be affixed only if the manufacturer or, where appropriate, his authorized representative established in the Community, has followed the applicable procedures in accordance with Article 11.

4. It is prohibited to affix marks which may be confused with the EC mark of conformity.

Article 18

Obligations of the notified body in the case of a wrongly affixed mark

Where it is found that the EC mark has been wrongly affixed, the notified body which carried out the assessment of conformity shall take appropriate measures and forthwith inform the competent Member State thereof. The competent Member State shall inform the other Member States and the Commission thereof.

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 to withdraw devices from the market, 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 obligations of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

Article 21

Guidelines

The Commission shall adopt the necessary guidelines for the uniform application of this Directive in respect in particular of:

(a) the scope of the Directive,
(b) the classification of devices,
(c) the conformity assessment procedures.

The Commission shall publish these guidelines in the Official Journal of the European Communities.

Article 22

Repeal and amendment of Directives

1. Directive 76/764/EEC is hereby repealed with effect from 1 July 1994.

2. In the title and Article 1 of Directive 84/539/EEC, the words "human or" are deleted.

3. The following paragraph 6 is added to Article 1 of Directive 90/385/EEC:

"6. The following provisions of Council Directive ../.../EEC[26] [on medical devices] also apply to active implantable medical devices: Article 1(2)(g) and (i); Article 11(6), (8) and (9); Article 13(1)(c) coupled with Article 7; Article 17(3); Article 19(2); Article 21 points (a) and (c) of the first paragraph."

Article 23

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 31 December 1993. They shall immediately inform the Commission thereof.

The standing committee referred to in Article 7 may assume its tasks from the date of notification of this Directive. The Member States may take the measures referred to in Article 16 within six months of 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 July 1994.

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.

(26)

3. Member States shall take the necessary action to ensure that the notified bodies which are responsible pursuant to Article 11(1) to (4) for the assessment of the conformity of devices already placed on the market prior to the implementation of this Directive take account of the results of tests and verifications already carried out under pre-existing national law in respect of such devices and of any other relevant information regarding the characteristics and performance of such devices.

4. In the case of devices which, for the purposes of this Directive, must be the subject of one of the procedures referred to in Annexes 2 to 6, 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 30 June 1994 during the period up to 30 June 1997. In the case of other devices lawfully placed on the market before 30 June 1994, Member States shall accept their being put into service during the period up to 30 June 1995.

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 24

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President

ANNEX 1

ESSENTIAL REQUIREMENTS

I. General requirements

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 the patients, users and, where applicable, other persons. The risks associated with the devices must be reduced to an acceptable level compatible with a high level of protection of health and safety.

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.

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

4. The characteristics and performances referred to in Sections 1 and 3 must not be adversely affected to such a degree that the clinical condition 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 are not adversely affected in the storage and transport conditions (temperature, humidity, etc.) laid down by the manufacturer.

6. Any undesirable side-effects must constitute acceptable risks when weighed against the performances intended.

II. Requirements regarding design and construction

7. Chemical and physical 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:

- 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.

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 completely safely with the materials, substances and gases with which they enter into contact during normal use or routine treatment.

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 65/65/EEC, and whose action in combination with the device can result in its bioavailability, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC, as last amended by Directive 89/341/EEC.

7.5 The devices must be designed and manufactured in such a way as to minimize the health risks posed by substances leaking from the device during use.

8. Infection and microbial contamination

8.1 The devices and manufacturing processes must be designed in such a way as to minimize the risk of infection to the patient. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.

8.2 Where a device incorporates animal or human tissues, the risks of cross-infection must be minimized by selecting appropriate tissues and using appropriate inactivation, conservation and test procedures.

8.3 Sterile devices 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.

8.4 Devices labelled sterile must have been sterilized by an appropriate, validated method.

8.5 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.

8.6 The packs and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile packaging.

9. Construction and environmental properties

9.1 If the device is intended for use in combination with other devices or equipment, 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 instruction leaflet.

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

- the risk of injury, in connection with their physical, including dimensional features;
- risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration;
- the risks of interference with other devices normally required for the investigations or for the treatment given;
- risks possibly arising from lack of maintenance and calibration, including:

  . ageing of the materials used,
  . 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 failsafe condition. Particular attention must be paid to devices which must be exposed to or used in association with flammable substances or 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 as specified by the manufacturer, taking account of the intended purpose of the device.

10.2 The units on 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), as last amended by Directive 89/617/EEC(2).

(1) OJ No L 39, 15.2.1980, p. 40.
(2) OJ No L 357, 7.12.1989, p. 28.

11. Protection against radiation

11.1 The devices must be designed and constructed in such a way that the radiation emitted will not attain dangerous levels. Where emission of dangerous levels of radiation is necessary for a specific medical purpose considered to outweigh the risks inherent in the emissions, it must be possible for the user to control the emissions.

11.2 Devices emitting ionizing radiation must be designed and constructed in such a way as:

(a) to ensure that the quantity and quality of radiation emitted can be adjusted and controlled;

(b) to reduce exposure of the user at work and all unnecessary exposure of the patient.

11.3 The operating instructions for devices emitting radiation must give detailed information on the nature of the devices, means of protecting the patient and user and on ways of avoiding mishandling and the risks inherent in installation.

11.4 Devices emitting radiation must be designed and manufactured in such a way as to reduce unnecessary exposure of the patient and of the user as far as possible.

11.5 Instruments, apparatus or appliances emitting radiation must be fitted with visual displays and/or audible warnings of radiation emissions.

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

12.1 Devices depending on software must be designed in such a way as to minimize the risks arising from errors in the program.

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 shall 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 The 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 vicinity.

12.6 Protection against electrical risks

The devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of 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 The 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 The 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 The 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 The 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 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 an interlock and/or alarm system to prevent and/or indicate any inadequacies in the flow rate which could pose a danger.

12.9 The function of the controls and visual displays must be clearly specified on the devices.

13. Information supplied by the manufacturer

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

This information comprises the details on the label and the data in the instruction leaflet.

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.

An instruction leaflet must be included in the packaging for every device.

By way of exception, no such instruction leaflet is needed for devices in Class I or Class IIa if they can be used completely safely without any such instructions.

13.2 Where appropriate, this information should take the form of symbols. Any symbols and identification colours 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:

(a) the name or trade name and address of the manufacturer;

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

(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 time limit for completely safe use, expressed as the year and month;

(f) where appropriate, an indication that the device is for single use;

(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.

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 instruction leaflet.

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 instruction leaflet must contain the following particulars:

(a) for devices in Class IIb or Class III the year of authorization to affix the EC mark;

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

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

(d) 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;

(e) 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 needed to ensure that the devices operate properly and safely at all times;

(f) where appropriate, information to avoid certain risks in connection with implantation of the device;

(g) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;

(h) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;

(i) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, resterilization, and any restriction on the number of reuses;

(j) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);

(k) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.

The instruction leaflet 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:

(l) precautions to be taken in the event of changes in the performance of the device;

(m) 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.;

(n) adequate information regarding the medicinal products which the device in question is designed to administer;

(o) precautions to be taken against any special, unusual risks related to the disposal of the device.

ANNEX 2

EC DECLARATION OF CONFORMITY

(FULL QUALITY ASSURANCE SYSTEM)

1. The manufacturer shall apply the quality system approved for the design, manufacture and final inspection of the products concerned, as specified in Sections 3 and 4, and shall be subject to the EC surveillance specified in Section 5.

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

   The manufacturer shall affix the EC mark in accordance with Article 17 and shall draw up a written declaration of conformity. This declaration shall cover a given number of identified specimens of the products manufactured and shall be kept by the manufacturer. The EC mark shall be accompanied by the identification number of the notified body which performs the tasks referred to in this Annex.

3. Quality system

3.1 The manufacturer shall lodge an application for assessment of his quality system with a notified body.

   The application shall include:

   - the name and address of the manufacturer;
   - all the relevant information on the product or product category covered by the procedure;
   - a written declaration that no application has been lodged with any other notified body for the same products;
   - the documentation on the quality system;
   - an undertaking to fulfil the obligations imposed by the quality system approved;
   - an undertaking to keep the approved quality system adequate and efficacious;

- an undertaking by the manufacturer to institute and keep updated a post-marketing surveillance system. This undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

  (i) any deterioration in the characteristics and/or performances of a device, as well as any inaccuracies in the instruction leaflet which might lead to or might have led to the death of a patient or user or to a serious deterioration in their state of health;

  (ii) any technical or medical reason connected with the device leading to recall of devices of the same type by the manufacturer.

3.2 Application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures. This quality system documentation must permit uniform interpretation of the quality policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

It shall include in particular an adequate description of:

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular:

- the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned;

- the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform;

(c) the procedures for monitoring and verifying the design of the products and in particular:

- a general description of the product, including any variants planned;

- the design specifications, including the standards which will be applied and a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to in Article 5 are not applied in full;

- the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed;

- if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer;

- a statement indicating whether or not the device incorporates, as an integral part, a substance as referred to in Section 7.4 of Annex 1 whose action in combination with the device may result in its bioavailability and data on the tests conducted in this connection;

- the clinical data referred to in Annex 10;

- the draft label and, where appropriate, instruction leaflet;

(d) the inspection and quality assurance techniques at the manufacturing stage and in particular:

- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents;

- the product-identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

(e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration of the test equipment adequately.

3.3 The notified body shall audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It shall presume that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team shall include at least one member with past experience of assessments of the technology concerned. The assessment procedure shall include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers to inspect the manufacturing processes.

The decision shall be notified to the manufacturer. It shall contain the conclusions of the inspection and a reasoned assessment.

3.4 The manufacturer shall inform the notified body which approved the quality system of any plan for substantial changes to the quality system.

The notified body shall assess the changes proposed and shall verify whether after these changes the quality system will still meet the requirements referred to in Section 3.2. It shall notify the manufacturer of its decision. This decision shall contain the conclusions of the inspection and a reasoned assessment.

4. Examination of the design of the product

4.1 In addition to the obligations imposed by Section 3, the manufacturer shall lodge an application for examination of the design dossier relating to the product which he plans to manufacture and which falls into the category referred to in Section 3.1.

4.2 The application shall describe the design, manufacture and performances of the product in question. It shall include the documents needed to assess whether the product conforms to the requirements of this Directive, as referred to in Section 3.2(c).

4.3 The notified body shall examine the application and, if the product conforms to the relevant provisions of this Directive, shall issue the applicant with an EC design-examination certificate. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the requirements of the Directive. The certificate shall contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design and, where appropriate, a description of the intended purpose of the product.

4.4 The applicant shall inform the notified body which issued the EC design-examination certificate of any significant change made to the approved design. Changes to the approved design must receive further approval from the notified body which issued the EC design-examination certificate wherever the changes could affect conformity with the essential requirements of the Directive or with the conditions prescribed for use of the product. This additional approval shall take the form of a supplement to the EC design-examination certificate.

5. Surveillance

5.1 The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

5.2 The manufacturer shall authorize the notified body to carry out all the necessary inspections and shall supply it with all relevant information, in particular:

- the documentation on the quality system;
- the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, etc.;
- the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, calibration and the qualifications of the staff concerned, etc.

5.3 The notified body shall periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and shall supply the manufacturer with an assessment report.

5.4 In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It shall provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

6. Administrative provisions

6.1 The manufacturer shall, for a period ending at least five years after the last product has been manufactured, keep at the disposal of the national authorities:

- the declaration of conformity;
- the documentation referred to in the fourth indent of Section 3.1;
- the changes referred to in Section 3.4;

- the documentation referred to in Section 4.2; and
- the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4, 5.3 and 5.4.

6.2 The notified body shall communicate to the other notified bodies all relevant information concerning the quality system approvals issued, refused or withdrawn.

7. Application to devices in Classes IIa and IIb

In line with Article 11(2) and (3), this Annex may apply to products in Classes IIa and IIb, subject to the following derogations:

7.1 For products in Class IIa, by way of derogation from the final indent of Section 3.1, the manufacturer shall undertake to notify the competent authorities of the incidents referred to in the abovementioned indent immediately on learning of them and to institute and keep updated an appropriate internal system for this purpose.

7.2 Section 4 shall not apply to products in Classes IIa and IIb.

ANNEX 3

EC TYPE-EXAMINATION

1. EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative sample of the production covered fulfils the relevant provisions of this Directive.

2. The application for EC type-examination shall be lodged by the manufacturer or by his authorized representative established in the Community with a notified body.

   The application shall include:

   - the name and address of the manufacturer and the name and address of the authorized representative if the application is lodged by the representative;

   - the documentation described in Section 3 needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the "type", with the requirements of this Directive. The applicant shall make a "type" available to the notified body. The notified body may request other samples as necessary;

   - a written declaration that no application has been lodged with any other notified body for the same type.

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

   - a general description of the type, including any variants planned;

- design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of components, sub-assemblies, circuits, etc.;

- the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product;

- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements if the standards referred to in Article 5 have not been applied in full;

- the results of the design calculations, investigations, technical tests, etc. carried out;

- a statement indicating whether or not the device incorporates, as an integral part, a substance as referred to in Section 7.4 of Annex 1 whose action in combination with the device may result in its bioavailability, and data on the tests conducted in this connection;

- the clinical data referred to in Annex 10;

- the draft label and, where appropriate, instruction leaflet.

4. The notified body shall:

4.1 examine and assess the documentation and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable provisions of the standards referred to in Article 5, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;

4.2 carry out or ask for the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer meet the essential requirements of this Directive if the standards referred to in Article 5 have not been applied; if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer;

4.3 carry out or ask for the appropriate inspections and the tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;

4.4 agree with the applicant on the place where the necessary inspections and tests will be carried out.

5. If the type conforms to the provisions of this Directive, the notified body shall issue the applicant with an EC type-examination certificate. The certificate shall contain the name and address of the manufacturer, the conclusions of the inspection, the conditions of validity and the data needed for identification of the type approved. The relevant parts of the documentation shall be annexed to the certificate and a copy shall be kept by the notified body.

6. The applicant shall inform the notified body which issued the EC type-examination certificate of any significant change made to the approved product.

Changes to the approved product must receive further approval from the notified body which issued the EC type-examination certificate wherever the changes may affect conformity with the essential requirements or with the conditions prescribed for use of the product. This new approval shall, where appropriate, take the form of a supplement to the initial EC type-examination certificate.

7. Administrative provisions

7.1 Each notified body shall communicate to the other notified bodies all relevant information on EC type-examination certificates and supplements issued, refused or withdrawn.

7.2 Other notified bodies may obtain a copy of the EC type-examination certificates and/or the supplements thereto. The annexes to the certificates shall be made available to the other notified bodies on reasoned application, after informing the manufacturer.

ANNEX 4

EC VERIFICATION

1. EC verification is the procedure whereby the manufacturer or his authorized representative established in the Community ensures and declares that the products which have been subjected to the procedure set out in Section 4 conform to the type described in the EC type-examination certificate and meet the requirements of this Directive which apply to them.

2. The manufacturer shall take all the measures necessary for the manufacturing process to ensure that the products conform to the type described in the EC type-examination certificate and to the requirements of the Directive which apply to them. Before the start of manufacture, the manufacturer shall prepare documents defining the manufacturing process, in particular as regards sterilization where necessary, together with all the routine, pre-established provisions to be implemented to ensure homogeneous production and, where appropriate, conformity of the products with the type described in the EC type-examination certificate and with the requirements of this Directive which apply to them. The manufacturer shall affix the EC mark in accordance with Article 17 and shall draw up a declaration of conformity.

3. The manufacturer shall undertake to institute and keep updated a post-marketing surveillance system. This undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

   (i) any deterioration in the characteristics and/or performances of a device, as well as any inaccuracies in the instruction leaflet which might lead to or might have led to the death of a patient or user or to a serious deterioration in their state of health;

(ii) any technical or medical reason connected with the device leading to recall of devices of the same type by the manufacturer.

4. The notified body shall carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Directive either by examining and testing every product as specified in Section 5 or by examining and testing products on a statistical basis as specified in Section 6, at the choice of the manufacturer.

5. Verification by examination and testing of every product

5.1 Every product shall be examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to verify, where appropriate, the conformity of the products with the type described in the EC type-examination certificate and with the requirements of the Directive which apply to them.

5.2 The notified body shall affix, or have affixed, its identification number to each approved product and shall draw up a written certificate of conformity relating to the tests carried out.

6. Statistical verification

6.1 The manufacturer shall present the manufactured products in the form of homogeneous batches.

6.2 A random sample shall be taken from each batch. The products which make up the sample shall be examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out to verify, where appropriate, the conformity of the products with the type described in the EC type-examination certificate and with the requirements of the Directive which apply to them in order to determine whether to accept or reject the batch.

6.3 Statistical control of products will be based on attributes, entailing a sampling system ensuring a limit quality corresponding to a probability of acceptance of 5%, with a non-conformity percentage of between 3 and 7%. The sampling method shall be established by the harmonized standards referred to in Article 5, taking account of the specific nature of the product categories in question.

6.4 If the batch is accepted, the notified body shall affix, or have affixed, its identification number to each product and shall draw up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform.

If a batch is rejected the competent notified body shall take appropriate measures to prevent the batch from being placed on the market. In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

The manufacturer may, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

7. Administrative provisions

The manufacturer or the manufacturer's authorized representative shall, for a period ending at least five years after the last product has been manufactured, keep at the disposal of the national authorities:

- the declaration of conformity;
- the documentation referred to in Section 2;
- the certificates referred to in Sections 5.2 and 6.4.

8. Application to devices in Class IIa

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

8.1 By way of derogation from Sections 1 and 2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex 7 and meet the requirements of this Directive which apply to them.

8.2 By way of derogation from Sections 1, 2, 5 and 6, the verifications conducted by the notified body are intended to confirm the conformity of the products in Class IIa with the technical documentation referred to in Section 3 of Annex 7.

8.3 By way of derogation from Section 3, the manufacturer or the manufacturer's authorized representative established in the European Community undertake to notify the competent authorities of the incidents referred to in the abovementioned Section immediately on learning of them and to institute and keep updated an appropriate internal system for this purpose.

ANNEX 5

EC DECLARATION OF CONFORMITY

(PRODUCTION QUALITY ASSURANCE)

1. The manufacturer shall apply the quality system approved for the manufacture of the products concerned and carry out the final inspection, as specified in Section 3, and shall be subject to the EC surveillance referred to in Section 4.

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

The manufacturer shall affix the CE mark in accordance with Article 17 and shall draw up a written declaration of conformity. This declaration shall cover a given number of identified specimens of the products manufactured and shall be kept by the manufacturer. The CE mark shall be accompanied by the identification number of the notified body which performs the tasks referred to in this Annex.

3. Quality system

3.1 The manufacturer shall lodge an application for assessment of his quality system with a notified body.

The application shall include:

- the name and address of the manufacturer;
- all the relevant information on the product or product category covered by the procedure;
- a written declaration that no application has been lodged with any other notified body for the same products;

- the documentation on the quality system;

- an undertaking to fulfil the obligations imposed by the quality system approved;

- an undertaking to keep the approved quality system adequate and efficacious;

- where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates;

- an undertaking by the manufacturer to institute and keep updated a post-marketing surveillance system. This undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

  (i) any deterioration in the characteristics and/or performances of a device, as well as any inaccuracies in the instruction?leaflet which might lead to or might have led to the death of a patient or user or to a serious deterioration in their state of health;

  (ii) any technical or medical reason connected with the device leading to recall of devices of the same type by the manufacturer.

3.2 Application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate. All the elements, requirements and provisions adopted by the manufacturer for his quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures. This quality system documentation must permit uniform interpretation of the quality policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

It shall include in particular an adequate description of:

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular:

- the organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned;
- the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of product, including control of products which fail to conform;

(c) the inspection and quality assurance techniques at the manufacturing stage and in particular:

- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents;
- the product-identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

(d) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration of the test equipment adequately.

3.3 The notified body shall audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It shall presume that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team shall include at least one member with past experience of assessments of the technology concerned. The assessment procedure shall include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers to inspect the manufacturing processes.

The decision shall be notified to the manufacturer after the final inspection. It shall contain the conclusions of the inspection and a reasoned assessment.

3.4 The manufacturer shall inform the notified body which approved the quality system of any plan for substantial changes to the quality system.

The notified body shall assess the changes proposed and shall verify whether after these changes the quality system will still meet the requirements referred to in Section 3.2. After receiving the abovementioned information it shall notify the manufacturer of its decision. This decision shall contain the conclusions of the inspection and a reasoned assessment.

4. Surveillance

4.1 The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

4.2 The manufacturer shall authorize the notified body to carry out all the necessary inspections and shall supply it with all relevant information, in particular:

- the documentation on the quality system;
- the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, calibration and the qualifications of the staff concerned, etc.

4.3 The notified body shall periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and shall supply the manufacturer with an assessment report.

4.4 In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It shall provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

5. Administrative provisions

5.1 The manufacturer shall, for a period ending at least five years after the last product has been manufactured, keep at the disposal of the national authorities:

- the declaration of conformity;
- the documentation referred to in the fourth indent of Section 3.1;
- the changes referred to in Section 3.4;
- the documentation referred to in the seventh indent of Section 3.1; and
- the decisions and reports from the notified body as referred to in Sections 4.3 and 4.4.

5.2 The notified body shall communicate to the other notified bodies all relevant information concerning the quality system approvals issued, refused or withdrawn.

6. Application to devices in Class IIa

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

6.1 By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex 7 and meet the requirements of this Directive which apply to them.

6.2 By way of derogation from the final indent of Section 3.1, the manufacturer shall undertake to notify the competent authorities of the incidents referred to in the abovementioned indent immediately on learning of them and to institute and keep updated an appropriate internal system for this purpose.

ANNEX 6

EC DECLARATION OF CONFORMITY

(PRODUCT QUALITY ASSURANCE)

1. The manufacturer shall apply the quality system approved for the final inspection and testing of the product, as specified in Section 3, and shall be subject to the surveillance referred to in Section 4.

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

The manufacturer shall affix the EC mark in accordance with Article 17 and shall draw up a written declaration of conformity. This declaration shall cover a given number of identified specimens of the products manufactured and shall be kept by the manufacturer. The CE mark shall be accompanied by the identification number of the notified body which performs the tasks referred to in this Annex.

3. Quality system

3.1 The manufacturer shall lodge an application for assessment of his quality system with a notified body.

The application shall include:

- the name and address of the manufacturer;
- all the relevant information on the product or product category covered by the procedure;
- a written declaration that no application has been lodged with any other notified body for the same products;

- the documentation on the quality system;
- an undertaking to fulfil the obligations imposed by the quality system approved;
- an undertaking to keep the approved quality system adequate and efficacious;
- where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates;
- an undertaking by the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

  (i) any deterioration in the characteristics and/or performances of a device, as well as any inaccuracies in the instruction leaflet which might lead to or might have led to the death of a patient or user or to a serious deterioration in their state of health;

  (ii) any technical or medical reason connected with the device leading to recall of devices of the same type by the manufacturer.

3.2 Under the quality system, each product shall be examined and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out to ensure that the products conform to the type described in the EC type-examination certificate and fulfil the provisions of this Directive which apply to them. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality system documentation must permit uniform interpretation of the quality programmes, quality plans, quality manuals and quality records.

It shall include in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the managerial staff with regard to product quality;
- the examinations and tests that will be carried out after manufacture; it must be possible to trace back the calibration of the test equipment adequately;
- the methods of monitoring the efficient operation of the quality system;
- the quality records, such as reports concerning inspections, tests, calibration and the qualifications of the staff concerned, etc.

3.3 The notified body shall audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It shall presume that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team shall include at least one member with past experience of assessments of the technology concerned. The assessment procedure shall include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers to inspect the manufacturing processes.

The decision shall be notified to the manufacturer. It shall contain the conclusions of the inspection and a reasoned assessment.

3.4 The manufacturer shall inform the notified body which approved the quality system of any plan for substantial changes to the quality system.

The notified body shall assess the changes proposed and shall verify whether after these changes the quality system will still meet the requirements referred to in Section 3.2. After receiving the abovementioned information it shall notify the manufacturer of its decision. This decision shall contain the conclusions of the inspection and a reasoned assessment.

4. Surveillance

4.1 The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

4.2 The manufacturer shall allow the notified body entrance for inspection purposes to the inspection, testing and storage locations and shall supply it with all relevant information, in particular:

- the documentation on the quality system;
- the technical documentation;
- the quality records, such as reports concerning inspections, tests, calibration and the qualifications of the staff concerned, etc.

4.3 The notified body shall periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the quality system and shall supply the manufacturer with an assessment report.

4.4 In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly and that the production conforms to the requirements of the Directive which apply to it. To this end, an adequate sample of the final products, taken on site by the notified body, shall be examined and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out. Where one or more of the samples fails to conform, the notified body shall take the appropriate measures. It shall provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

5. Administrative provisions

5.1 The manufacturer shall, for a period ending at least five years after the last product has been manufactured, keep at the disposal of the national authorities:

- the declaration of conformity;
- the documentation referred to in the seventh indent of Section 3.1;
- the changes referred to in Section 3.4; and
- the decisions and reports from the notified body as referred to in the final indent of Section 3.4 and in Sections 4.3 and 4.4.

5.2 The notified body shall communicate to the other notified bodies all relevant information concerning the quality system approvals issued, refused or withdrawn.

6. Application to devices in Class IIa

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

6.1 By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex 7 and meet the requirements of this Directive which apply to them.

ANNEX 7

EC DECLARATION OF CONFORMITY

1. The EC declaration of conformity is the procedure whereby the manufacturer or his authorized representative established in the Community who fulfils the obligations imposed by Section 2 and, in the case of sterile products and measuring devices, the obligations imposed by Section 5 ensures and declares that the products concerned meet the provisions of this Directive which apply to them. The manufacturer may affix the CE mark to each product in accordance with Article 17. The manufacturer shall draw up a written declaration of conformity.

2. The manufacturer shall establish the technical documentation described in Section 3. The manufacturer or his authorized representative established in the Community shall keep this documentation, including the declaration of conformity, at the disposal of the national authorities for inspection purposes for a period ending at least five years after the last product has been manufactured.

   Where neither the manufacturer nor his authorized representative are established in the Community, this obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market.

3. The technical documentation must allow assessment of the conformity of the product with the requirements of the Directive. It shall include in particular:

   - a general description of the product, including any variants planned;
   - design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc.;

- the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product;
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 have not been applied in full;
- in the case of sterile products, a description of the methods used;
- the results of the design calculations and of the inspections carried out, etc. If the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer;
- the test reports and, where appropriate, clinical data.

4. The manufacturer shall take all the measures necessary for the manufacturing process to ensure that the products manufactured conform to the technical documentation referred to in Section 3 and to the requirements of the Directive which apply to them.

5. In the case of products placed on the market in sterile condition and of measuring devices, the manufacturer must observe not only the provisions laid down in this Annex but also one of the procedures referred to in Annexes 4, 5 or 6. Application of the abovementioned Annexes and the intervention by the notified body shall be limited to:

- in the case of sterile products, only the aspects of manufacture concerned with obtaining sterile conditions;
- in the case of measuring devices, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Section 6.1 of this Annex shall apply.

6. Application to devices in Class IIa

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

6.1 Where this Annex is applied in conjunction with the procedure referred to in Annex 4, 5 or 6, the declaration of conformity referred to in Section 1 of this Annex and the declaration of conformity referred to in the other abovementioned Annexes shall form a single declaration. As regards the declaration based on this Annex, the manufacturer shall ensure and declare that the product design meets the provisions of this Directive which apply to it.

ANNEX 8

STATEMENT CONCERNING DEVICES FOR SPECIAL PURPOSES

1. For custom-made devices or for devices intended for clinical investigations the manufacturer or his authorized representative established in the Community shall draw up the statement containing the information stipulated in Section 2.

2. The statement shall contain the following information:

2.1 For custom-made devices:

- data allowing identification of the device in question;
- a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient;
- the name of the medical specialist or other authorized person who made out the prescription and, where applicable, the name of the clinic concerned;
- the particular features of the device as specified in the relevant medical prescription;
- a statement that the device in question conforms to the essential requirements set out in Annex 1 and, where applicable, indicating which essential requirements have not been fully met, together with the grounds.

2.2 For devices intended for the clinical investigations covered by Annex 10:

- data allowing identification of the device in question;
- an investigation plan stating in particular the purpose, scope and number of devices concerned;
- the opinion of the Ethics Committee concerned and details of the aspects covered by its opinion;

- the name of the medical specialist or other authorized person and of the institution responsible for the investigations;
- the place, starting date and scheduled duration for the investigations;
- a statement that the device in question conforms to the essential requirements apart from the aspects covered by the investigations and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient.

3. The manufacturer shall also undertake to keep available for the competent national authorities:

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

The manufacturer shall take all the measures necessary for the manufacturing process to ensure that the products manufactured conform to the documentation mentioned in the first paragraph.

3.2 For devices intended for clinical investigations, the documentation shall contain:

- a general description of the product;
- design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of components, sub-assemblies, circuits, etc.;
- the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product;
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Directive if the standards referred to in Article 5 have not been applied;
- the results of the design calculations, and of the inspections and technical tests carried out, etc.

The manufacturer shall take all the measures necessary for the manufacturing process to ensure that the products manufactured conform to the documentation referred to in the first paragraph of this Section.

The manufacturer may authorize the assessment, or audit where necessary, of the effectiveness of these measures.

ANNEX 9

CLASSIFICATION CRITERIA

I. CLASSIFICATION RULES

1. Non-invasive devices

1.1 Rule 1

All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.

1.2 Rule 2

All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa:

- if they are connected to an active medical device in Class IIa or a higher class;
- if they are used for storing blood or other body liquids or tissues.

In all other cases they are in Class I.

1.3 Rule 3

All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat or solute, in which case they are in Class IIa.

1.4 Rule 4

All non-invasive devices which come into contact with injured skin are in Class I if they are intended to be used as a mechanical barrier, for compression, for the absorption of exudates or for moisture permeability.

They are in Class IIb if they are intended to be used principally for third-degree burns or other skin injuries of comparable degree.

In all other cases they are in Class IIa.

2. Invasive devices

2.1 Rule 5

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

- are in Class I if they are intended for transient use;
- are in Class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in the anterior nostrils or the external ear canal up to the ear drum, in which case they are in Class I;
- are in Class IIa if they are intended for long-term use.

All invasive devices with respect to body orifices, other than surgically invasive devices intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.

2.2 Rule 6

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

- intended to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III;
- reusable surgical instruments, in which case they are in Class I.

2.3 Rule 7

All surgically invasive devices intended for short-term use are in Class IIa unless they are intended:

- either to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III;
- or for use in direct contact with the central nervous system, in which case they are in Class III.

2.4 Rule 8

All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended:

- to be placed in the teeth, in which case they are in Class IIa;
- to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III;
- to undergo chemical change in the body, to be biologically active, to be wholly or mainly absorbed, to supply energy in the form of ionizing radiation or to administer medicines, in which case they are in Class III, except if the devices are placed in the teeth.

3. Active devices

3.1 Rule 9

All active therapeutical devices intended to supply energy or to administer, sample or exchange substances are in Class IIa unless they are intended:

- to administer potentially dangerous levels or forms of energy to the human body, taking account of the part of the body absorbing the energy and/or the density of the energy;
- to administer or exchange medicines, body liquids or other substances in a potentially dangerous way, taking account of the nature of the substances administered and of the part of the body concerned, or in such a way that the exchange or flow cannot be controlled by the patient.

In these cases, the devices are in Class IIb. All active devices intended to control and monitor the performance of active therapeutical devices in Class IIb or intended directly to influence the performance of such devices are in Class IIb.

3.2 Rule 10

All active devices intended for diagnosis are in Class IIa:

- if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum;
- if they are intended primarily to allow direct diagnosis of vital physiological processes in a situation posing an immediate danger to the patient's life.

3.3 Rule 11

All other active devices are in Class I.

4. Special rules

4.1 Rule 12

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 65/65/EEC, and whose action in combination with the devices can result in its bioavailability, are in Class III.

4.2 Rule 13

All devices used for contraception or the prevention of the transmission of a viral disease by sexual contact are in Class IIb.

II. DEFINITIONS AND IMPLEMENTING RULES

1. DEFINITIONS FOR THE CLASSIFICATION RULES

1.1 Duration

Transient — Normally intended for continuous use for less than 60 minutes.

Short term — Normally intended for continuous use for not more than 30 days.

Long term — Normally intended for continuous use for more than 30 days.

1.2 Invasive devices

Invasive device — A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

Body orifice — Any natural opening in the body, including the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

Surgically invasive device — A device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

1.3 Reusable surgical instrument

Instrument intended for a surgical operation such as cutting, drilling, sawing, scratching, retracting or clipping without connection to any other medical device and which can be used in several different operations.

1.4 Active medical device — Any medical device connected to or equipped with a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices.

1.5 Active therapeutical device — Any active medical device, whether used alone or in combination with other medical devices, to support, modify or replace biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

1.6 Active device for diagnosis — Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

1.7 Central circulatory system — The following vessels:
arteriae pulmonales, aorta ascendens, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior.

1.8 Central nervous system — Brain and spinal cord.

2. IMPLEMENTING RULES

2.1 Application of the classification rules shall be governed by the intended purpose of the devices.

2.2 If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.

2.3 If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical use.

2.4 If two rules apply to the same device, based on the performance specified for the device by the manufacturer, the rule resulting in the higher classification shall apply.

ANNEX 10

CLINICAL EVALUATION

1. General provisions

1.1 As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Section 1 of Annex 1 under the normal conditions of use of the device and the evaluation of the undesirable side-effects must be based on clinical data in the case of implantable devices, devices in Class III and, where justified, other devices. Taking account of any relevant harmonized standards, where appropriate, the adequacy of the clinical data shall be based on:

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

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

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

2. Clinical investigation

2.1 Objectives

The objectives of clinical investigation are:

- to verify that, under normal conditions of use, the performances of the devices conform to those referred to in Section 3 of Annex 1; and
- to determine any undesirable side-effects, under normal conditions of use, and assess whether they are risks when weighed against the intended performance of the device.

2.2 Ethical considerations

Clinical investigations shall be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the 41st World Medical Assembly in Hong Kong in 1989. It is mandatory that all measures relating to the protection of human subjects are carried out in the spirit of the Helsinki Declaration. This shall include every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.

2.3 Methods

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

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

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

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

2.3.5 All adverse incidents shall be fully recorded.

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

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

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

ANNEX 11

MINIMUM CRITERIA FOR THE DESIGNATION OF NOTIFIED INSPECTION BODIES

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

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

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

3. The notified body must be able to carry out all the tasks assigned to such bodies by one of Annexes 2 to 6 and for which it has been notified, whether these tasks are carried out by the body itself or on its responsibility. In particular, it must have the necessary staff and possess the facilities needed to perform properly the technical and administrative tasks entailed in assessment and verification. It must also have access to the equipment necessary for the verifications required.

4. The inspection staff must have:

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

- satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections;

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

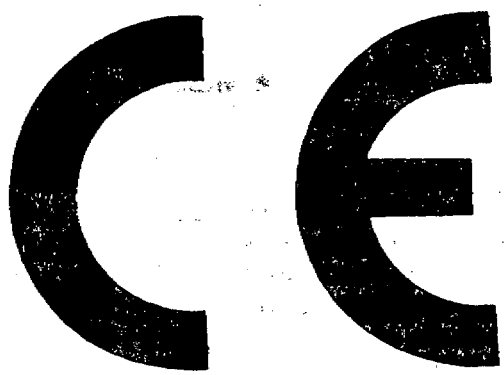
5. The impartiality of the inspection staff must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of the inspections.

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

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

ANNEX 12

CE MARK OF CONFORMITY



FICHE FINANCIERE

VOLET 1 : IMPLICATIONS FINANCIERES

1. **Intitulé de l'action**

   Proposition de directive concernant le rapprochement des législations des Etats membres relatives aux dispositifs médicaux.

2. **Lignes budgétaires concernées**

   article B 5-300 : actions relatives à l'achèvement du Marché Intérieur, dépenses opérationnelles
   article B 8-530 : actions relatives à l'achèvement du Marché Intérieur, dépenses d'appui et de soutien.

3. **Base légale**

   Article 100A du Traité CEE

4. **Description de l'action**

   4.1. Achèvement du Marché Intérieur dans le secteur des dispositifs médicaux; amélioration de la protection de la santé et de la sécurité des patients et des utilisateurs.

   En suivant les principes de la Nouvelle Approche, la directive harmonise les exigences et les procédures d'évaluation de conformité auxquelles doivent répondre les dispositifs médicaux lors de leur mise sur le marché et de leur mise en service. La mise en oeuvre efficace implique auprès de la Commission, des Etats membres et des organismes européens de normalisation CEN/CENELEC des activités dans les domaines suivants :

   - établissement des normes harmonisées par le CEN/CENELEC facilitant la preuve de la conformité aux exigences essentielles de la directive,
   - mise en place par les Etats membres d'une infrastructure d'autorités compétentes assurant le contrôle du respect de la directive ainsi que la désignation par les Etats membres des organismes de certification chargés de l'évaluation de la conformité,

- établissement et gestion d'un système d'alerte permettant aux Etats membres de prendre des mesures de protection suite à des incidents indésirables intervenus avec des dispositifs,
- élaboration par la Commission des lignes directrices utiles à l'application uniforme de la directive portant sur son champ d'application ainsi que sur la classification des dispositifs,
- gestion des procédures concernant la classification des dispositifs et l'application de la clause de sauvegarde impliquant le recours à l'avis technique des experts,
- mise en place d'une base européenne de données portant sur la certification des dispositifs, la classification et les incidents notifiés dans le cadre du système d'alerte.

4.2. Durée : environ 4-5 ans; action ponctuelle. Le montant des crédits alloués pour cette action sera toutefois déterminé chaque année en fonction des travaux restant à effectuer.

4.3. Population concernée : potentiellement, l'ensemble de la population communautaire et des pays tiers.

5. **Classification des dépenses**

5.1. Dépenses non obligatoires

5.2. . B5-300 : crédits dissociés
. B8-530 : crédits non dissociés

6. **Nature des dépenses**

L'élaboration des normes harmonisées par le CEN/CENELEC est couverte par une contribution financière de la Communauté et l'AELE (part du financement incombant à la CE : 86%, à l'AELE : 14%). Les frais restant seront couverts par les organismes de normalisation et les parties concernées (industrie, organismes de certification etc).

Le financement sera octroyé moyennant des bons de commande passés en vertu du contrat-cadre du 4 août 1989 signé avec le CEN/CENELEC.

La mise en place d'une base de données nécessitera un financement sous forme d'étude de faisabilité et de prestation de services au cours de la phase de démarrage.

La fourniture des avis techniques nécessaires en vue des questions spécifiques dans le cadre de la gestion courante sera financée par des contrats d'étude et de prestation de service.

7. **Incidence financière sur les crédits d'intervention (partie B du budget)**

a) élaboration des normes européennes (CD)

1. Mode de calcul

Le financement sera déterminé en fonction des travaux à confier aux contractants. Il sera calculé sur la base de l'unité "homme/mois", qui s'élève actuellement à 8.000 ECU.

Le nombre de normes harmonisées nécessaires jusqu'à fin 1996 est de 300. La contribution de la Commission est estimée à 6,25 hommes/mois par norme;
Frais totaux : 1.875 hommes/mois, soit 15 mio ECU

2. L'échéancier indicatif des crédits pourrait être le suivant :

	Crédits d'engagement (1.000 ECU)	Crédits de paiement (1.000 ECU)
1992	1.500	1.000
1993	4.000	2.000
1994	5.000	4.000
1995	4.500	5.000
1996	p.m.	3.000
	15.000	15.000

Le niveau des crédits à partir de 1992 sera fixé par la procédure budgétaire annuelle dans le cadre des contraintes fixées par les Perspectives financières post 92.

Pour 1992, le montant global (mini-budgets compris) est inclus dans le chiffre total des dépenses de - Notification, reconnaissance mutuelle, harmonisation des législations techniques, normalisation et rectification et essais (33.153.000) de la fiche financière globale des postes B5-300 et B8-530.

b) autres mesures financées par le mini-budget conformément à la décision de la Commission du 22.5.1990 sur les mini-budgets
- frais d'experts : 450 à 500 ECU par expert, par jour

		ECU
* 1992	: 30 x 450 ECU	13.500
* 1993	: 30 x 450 ECU	13.500
* 1994	: 30 x 450 ECU	13.500
* 1995	: 20 x 500 ECU	10.000
* 1996	: 20 x 500 ECU	10.000
	TOTAL (1992-1996)	60.500

- frais pour la mise en place et le démarrage de la base de données, à répartir en trois tranches sur les années 1992 à 1994 :

	ECU
* 1992 :	200.000
* 1993 :	200.000
* 1994 :	100.000
TOTAL (1992-1994)	500.000

8. **Dispositions anti-fraude prévues dans la proposition d'action?**

Le contrat-cadre visé sous le point 6. prévoit un échelonnement des paiements en fonction des progrès des travaux, ainsi que la possibilité d'un audit par la Commission ou la Cour des Comptes.

VOLET 2 : DEPENSES ADMINSTRATIVES (partie A du budget)

L'action proposée implique une augmentation du personnel statutaire affecté à la gestion de la directive. Les procédures décisionnelles portant sur la classification des dispositifs et sur la clause de sauvegarde, le suivi de la normalisation européenne présupposent l'existence d'effectifs pouvant établir des analyses et avis technico-juridiques et en organiser la gestion administrative.

Les besoins en personnel sont à pourvoir, soit par voie de redéploiement interne, soit par décision de la Commission allocation ressources dans le cadre de la procédure budgétaire. Ils sont estimés, pour l'unité III.D.4, à partir de 1992 à :

- 1 A
- 1 B

soit environ 200.000 ECU, à raison de 100.000 ECU en moyenne par personne et par an.

VOLET 3 : ELEMENTS D'ANALYSE COUT-EFFICACITE

1. **Objectifs et cohérence avec la programmation financière**

La directive de type Nouvelle Approche s'inscrit dans le cadre de l'achèvement du Marché Intérieur. Le renvoi aux normes harmonisées fait partie de l'action pluriannuelle de la Commission qui consiste à soutenir le renforcement et l'élargissement de la normalisation européenne.

L'action est prévue dans la programmation financière de la DG III.

2. Justification de l'action

Les divergences dans les systèmes nationaux en ce qui concerne les exigences pour les produits et les procédures relatives à la mise sur le marché entraînent un gaspillage énorme de ressources humaines et financières à charge des fabricants et des Etats membres.

Les procédures communautaires permettront d'éviter la répétition multiple des procédures visant le même objet. De plus, les exigences harmonisées permettront à l'industrie de réaliser des économies sur le prix par unité de production, ce qui pourra même avoir un effet bénéfique sur les dépenses à charge des systèmes de santé publique.

Quant à l'harmonisation des normes, l'action vise à mettre en commun les ressources et, de ce fait, à éviter la multiplication des dépenses pour l'ensemble des Etats membres.

Globalement, les ressources requises à imposer au budget communautaire ne représentent qu'une part mineure par rapport à la totalité des ressources qui, de la part des Etats membres et des parties concernées, seront allouées dans la suite de l'action au bénéfice commun.

3. Suivi et évaluation de l'action

3.1. Indication des performances :

- degré d'harmonisation au plan de la normalisation (nombre de normes),
- nombre de certifications effectuées,
- nombre de rapports notifiés sur des incidents indésirables,
- nombre de procédures de clause de sauvegarde.

3.2. Modalités des évaluations :

- rapports d'état des progrès périodiques sur la normalisation dans le cadre de la directive du Conseil 83/189/CEE ayant au minimum un caractère annuel;
- échanges de vues dans un Comité sectoriel "dispositifs médicaux".

3.3. Principaux facteurs d'incertitude :

- la désignation des organismes de certification par les Etats membres se fait sur une base facultative et de manière décentralisée,
- l'assurance d'une application homogène d'un tel système présuppose, aussi bien auprès des Etats membres que sur le plan communautaire, la disponibilité d'interfaces assurant le fonctionnement des procédures.

Fiche d'évaluation d'impact

Impact de la proposition sur les entreprises et, en particulier, sur les petites et moyennes entreprises

TITRE DE LA PROPOSITION

Proposition de directive concernant le rapprochement des législations des Etats membres relatives aux dispositifs médicaux.

NUMERO DE REFERENCE DU DOCUMENT

2121.21

LA PROPOSITION

1. Compte tenu du principe de subsidiarité, pourquoi une législation communautaire est-elle nécessaire dans ce domaine et quels sont ses principaux objectifs?

Les réglementations nationales relatives à la mise sur le marché et la mise en service des dispositifs médicaux présentent un tel degré de divergences substantielles, qu'une libre circulation dans la Communauté n'est pas assurée. L'harmonisation des exigences et des procédures d'évaluation de la conformité auxquelles doivent répondre les dispositifs médicaux pour assurer la protection des patients, utilisateurs et tiers est, dès lors, le seul moyen pour achever le marché intérieur dans ce secteur.

IMPACT SUR LES ENTREPRISES

2. Qui sera affecté par la proposition?

- secteurs d'entreprises : tout fabricant de dispositifs médicaux (à l'exception des dispositifs implantables actifs, tels que des stimulateurs cardiaques ainsi que des dispositifs destinés au diagnostic in-vitro), exemples : appareils électromédicaux, produits à usage unique, matériaux et prothèses dentaires, prothèses orthopédiques, instruments, etc

- tailles des entreprises : toute taille, y compris les multinationales et les PME

- zones géographiques particulières d'implantation : aucune

3. Quelles mesures les entreprises devront-elles prendre pour se conformer à la proposition?

A partir de l'application totale de la directive, c'est-à-dire le 1er juillet 1997 :
- la conception et la fabrication des produits devront répondre aux exigences de la directive,
- les fabricants ou leurs mandataires devront suivre les procédures d'évaluation de conformité prévues.

Au cours d'une période de trois ans à partir de la première application de la directive (entre juin 1994 et juin 1997), les fabricants pourront, soit continuer à appliquer les législations nationales préexistantes, soit se conformer au régime harmonisé.

Quant aux procédures d'évaluation de conformité, les fabricants pourront choisir, en cas d'intervention d'une tierce partie, entre trois ou quatre procédures alternativement applicables.

Les dispositions transitoires ainsi que le choix pour les fabricants entre plusieurs procédures d'évaluation de la conformité devront faciliter la transition vers le régime harmonisé.

4. Quels effets économiques la proposition est-elle susceptible d'avoir?

- sur l'emploi : aucun effet significatif n'est escompté.

- sur les investissements et la création de nouvelles entreprises : la directive peut avoir comme effet, notamment en ce qui concerne les dispositifs médicaux présentant un risque élevé, qu'une partie des entreprises doivent adapter leurs procédés de fabrication, de sorte à permettre une qualité de production élevée et constante. Or, ces investissements renforceront la compétitivité des entreprises.

- sur la compétitivité des entreprises : l'action proposée facilitera l'accès à un marché de dimension communautaire. Cette perspective ouvrira de nouveaux horizons aux entreprises de taille plus modeste qui ne disposent pas de filiales dans chaque Etat membre pour traiter directement avec les autorités nationales compétentes. Il faut également souligner que les entreprises devront, de ce fait, faire face à une intensification de la concurrence.

5. La proposition contient-elle des mesures visant à tenir compte de la situation spécifique des petites et moyennes entreprises?

Non.

CONSULTATION

Pour préparer cette proposition, la Commission a organisé, depuis 1989, au moins cinq réunions rassemblant les experts gouvernementaux et les fédérations professionnelles. De plus, de multiples réunions bilatérales avec les fédérations sur des aspects spécifiques ont eu lieu.

Ont été consultées :

- les associations européennes de l'industrie des dispositifs médicaux,
- les associations des utilisateurs, notamment des médecins et des pharmaciens.

La Commission a, dans une large mesure, tenu compte des commentaires reçus lors de la consultation. Les milieux intéressés, y compris les fédérations industrielles, ont principalement supporté l'approche suivie dans la proposition.

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