COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 12 December 1988

Proposal for a

COUNCIL DIRECTIVE

on the approximation of the laws of the Member States relating to active implantable electromedical equipment.

(presented by the Commission)

Active implantable electromedical equipment (AIEME)

Explanatory memorandum

I. General

1. Scope

This proposal for a Directive has been produced pursuant to the Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards(1). It forms part of the programme of work laid down in the White Paper on the completion of the internal market by the end of 1992.

It applies to the safety of active implantable electromedical equipment, hereinafter referred to as "implants", i.e. electromedical equipment for therapeutic or diagnostic purposes permanently implanted in the human body by means of a surgical operation and using an electrical energy source consisting of a battery which is also implanted or located outside the body. The cardiac stimulator is the best known example of this kind of equipment, which consists of the following major subdivisions :

a) cardiac stimulation :
   - simple impulse generators
   - complex impulse generators
   - antitachycardiac devices

b) defibrillation

c) the implantable artificial heart

(1) OJ C 136, 4.6.1985, p. 1.

d) biostimulation :
   - of the nervous system
   - of the vascular system
   - of the ear
   - of the diaphragm
   - of the bladder
   - of the skeletal system
   - of the peripheral muscles
   - other forms

e) input of an active substance
   - with or without a closed loop
   - sensors

f) active implantable organs

g) others, in particular :
   - implantable monitoring devices.

In view in particular of the energy source which they use, implants are a special category of electromedical equipment justifying the preparation of a specific Directive to harmonize the national regulations on their safety and manufacture. The Directive therefore serves two purposes : the introduction of Community legislation on patient safety and the removal of the barriers to trade arising from the differences between the national regulations.

2. Justification for harmonization

Before starting work on the preparation of the proposal, the Commission conducted a detailed survey to examine the national regulations in the field of electromedical equipment in general and implants in particular.

The findings of the survey confirmed that there are major differences between the Member States, not only as regards the technical specifications on the design of electromedical equipment, but also as regards the administrative procedures for the examinations, tests, inspections and authorizations required for the marketing, use and implantation of implants.

One of the features of this sector and a justification for harmonizing the national regulations concerned is the degree of risk posed by implants and the different approaches adopted by the Member States as regards the means of protection of patients against such potential risks.

The national regulations on implants often, for traditional reasons, form part of the more general provisions applicable to medical equipment and pharmaceutical products and do not always take full account of an important feature in the field of implants, i.e. the fast rate of innovation resulting from medical research.

Broadly speaking, there are two different approaches in the Community as regards the various means of ensuring patient safety. On the one hand, there are systems in which major importance is attached to inspection of equipment before it is placed on the market by means of type approval and/or certification procedures and, on the other hand, there is the approach which on the whole consists of verifying that firms are able to guarantee a constant level of product safety, this mainly taking the form of "good-manufacturing practice" (GMP) or other quality assurance systems.

These differences in approach are due to different concepts of safety and for this reason it is inevitable that recourse to Article 100A of the EEC Treaty will have to be made to abolish the technical barriers to trade which will inevitably arise in view of the nature of the products concerned.

In conformity with Article 100A, paragraph 3, this proposal contains the necessary provisions in order to guarantee a high level of protection to the patients and other concerned categories.

The role and importance of national standards is clearly inversely proportional to that of intervention in the form of regulations. European standards are more or less non-existent.

It is clearly very difficult to assess the direct economic impact of such barriers and to calculate the cost. Economic analysis would make it possible to evaluate the additional costs which exporting companies would incur as a result of "non-harmonization", but would not necessarily shed light on any other adverse consequences.

However, the development of the internal market cannot be seen solely in macroeconomic terms of overall growth as a function of turnover in the sector alone. It must also be seen from the two angles of technological dynamism and the improvement of living conditions in the Community. The economic and social aspects are therefore closely interlinked and must be taken into consideration within the framework of an integrated approach.

It is thus particularly important that harmonization in the field of implants should proceed in a manner which expedites marketing as far as possible while offering the patient the maximum guarantee in terms of safety. In this way, the rapid distribution of high-technology products will benefit both industry, in which the rate of innovation will thus be increased, and the patient, who will benefit from an improvement in his health and a prolonged active life without having to wait for the most advanced equipment.

3. Consultation of the parties concerned

From the beginning of the preparatory work, the Commission's concern has been to involve all the parties concerned, that is to say government representatives, manufacturers, doctors specialized in implantation techniques and representatives of the European standards bodies CEN and CENELEC.

The main objective of the consultation procedure has been to try to find the best possible solutions and to keep, as far as possible, to the spirit and the letter of the Council Resolution of 7 May 1985, while taking account of the specific requirements of a relatively narrow and specific field of application and of the complexity of the various safety aspects.

4. Links with other harmonization systems

4.1. Harmonization in the field of electromedical equipment began with the adoption of Council Directive 84/539/EEC.

This Directive, which was prepared in the conventional manner, refers to a world standard, IEC Publication 601-1, which is endorsed by CENELEC and which lays down in a detailed manner the general safety requirements for all electromedical equipment. The specific requirements that may have to be laid down for certain specific categories of equipment are determined by other standards based on the above standard. The scope of Directive 84/539/EEC has been confined to those categories of equipment for which conformity with IEC standard 601-1 and the general requirements it lays down was considered to be sufficient to guarantee the safety of the patient and the users of such equipment.

4.2. This draft concerns a category of equipment which is to some extent on the fringe of electromedical equipment as a whole. The first difference concerns the energy source which, in the case of implants, will nearly always be an electric cell contained within the equipment itself, whereas all other medical equipment, including the equipment covered by Directive 84/539/EEC, operates on the main power supply system or a similar power source.

The second major difference is that implants are by definition introduced into the human body, in particular in order to regulate the vital functions.

The very low-voltage energy source and the invasive character of implants therefore mean that very specific safety considerations will be required and these will be reflected in standards which will not necessarily be subordinate to IEC Publication 601-1.

The safety requirements will, on the other hand, also have to take account of aspects not associated with the use of electricity, such as sterility, biocompatibility and operational reliability.

4.3. Other categories of medical equipment which are not covered either by Directive 84/539/EEC or by this draft are the subject of preparatory work which is being carried out in close cooperation with the parties concerned.

4.4. Harmonization of non-electrical medical equipment has been the subject of preparatory contacts with the parties concerned.

4.5. This draft follows on to the harmonization in the field of medical equipment already achieved in the form of Directive 84/539/EEC. It is planned to harmonize the sector completely within the time limits laid down in the White Paper.

5. Progress in standardization

An ISO/IEC joint working group has been working for several years at world level on one of the categories of equipment falling within the scope of this draft, namely implantable cardiac stimulators.

On this basis and on that of the essential safety requirements annexed to this draft, CENELEC adopted on March 1st 1988 European standard EN 50061 relating to cardiac stimulators. A large part of its technical content applies to implants as a whole for which it may be easier and faster to prepare draft European standards.

6. Closeness to the text of the "model directive"
(Annexed to the Resolution of 7 May 1985)

As with other proposals for directives based on the new approach, the Commission has tried to keep as close as possible to the "model directive" given in the Annex to the Resolution of 7 May 1985, while taking account of the information and opinions gathered during the consultation of the interested parties.

A. The basic approach to the production of the dossier that shall be evaluated by the notified body(2) in order to ascertain the conformity of the device to the directive, can be reduced to the production of three sub documents :

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(2) For "notified body" we intend a body that has been notified to the Commission by each Member State as responsible for controls and use of the Directive. This body shall not be necessarily of the same nationality of the Member State that notified it, and it can delegate to laboratories (either national or of another Member State) the duty of making tests, controls, surveillance that however will stay under its own responsibility.

1. Quality system dossier for sterility
2. Clinical evidence dossier
3. Technical safety dossier(3).

B. In the first document the manufacturer shall disclose all the informations related to the quality system that is implemented in his factory to ensure the sterility of the device. This system should be based on CEN 29001 and could be implemented by means of the use of a relevant guide to good-manufacturing practice (GMP). Where a registration and control system of manufacturers using such guide exists, document 1 could simply be a certificate to that extent.

C. In the second document, the manufacturer shall disclose all the informations related to the tests and the means used to verify, from a clinical point of view, the performances and the principle of operation of the device. This document shall be countersigned by a specific consultant specialist of the pathology that the device is intended to treat or monitor.
Literature on the principles of operation, if any, should be enclosed.

D. Document 3 needs a more detailed description.

The first question arising is :

"Is there any relevant harmonized standard for the device under consideration covering the essential safety requirements, or is there any relevant national standard published on the Official Journal of the European Communities ?"

(3) see enclosed block diagrams

1. If the answer is "no" or if the manufacturer chooses not to apply them, then document 3 shall contain all the information related to the methods that the manufacturer has used to produce the device in conformity to the essential safety requirements, the tests done to verify it and a rationale explaining the consistency of such methods and tests with the essential safety requirements.
   For example in the above mentioned rationale reference could be made to specific requirements and tests contained in standards applicable to devices similar to the one considered.
   In this case the dossier shall be accompanied by a sample of the device.

2. If the answer is "yes" then two types of document can be generated :

   a) if the manufacturer applies a GMP he shall disclose his quality system together with the reference to the standards applied,

   b) if the manufacturer does not apply a GMP, he shall disclose in detail how he has tested the device to claim its conformity to it (a certificate of conformity made by a third party is also suitable for this purpose).

E. Once the dossier is then completed, it shall be presented to the notified body of <u>one</u> Member State. Depending on the way document 3 has been generated, the notified body will issue, after examination, one of the following certificates :

1) Pattern approval certificate, if the manufacturer has submitted document 3 according to point D.1.

2) Dossier approval certificate, if the manufacturer has submitted document 3 according to point D.2.

F. At this moment, the manufacturer can sell freely his device through EEC without the need of additional controls if it conforms to either the pattern or the dossier approved.

To do so, the manufacturer shall declare that the device conforms to the pattern or the dossier approved and shall label the device with the EC mark.

In order to be allowed to make the above declaration the manufacturer shall have either :

- an approval of his quality system for design, purchase, manufacture, final test and inspection based on CEN 29001 and the relevant GMP, or

- an approval of his quality system for purchase, manufacture, final test and inspection based on CEN 29002, or

- a certificate of inspection, made under the authority of the notified body; stating that the production conforms to the pattern or the design approved.

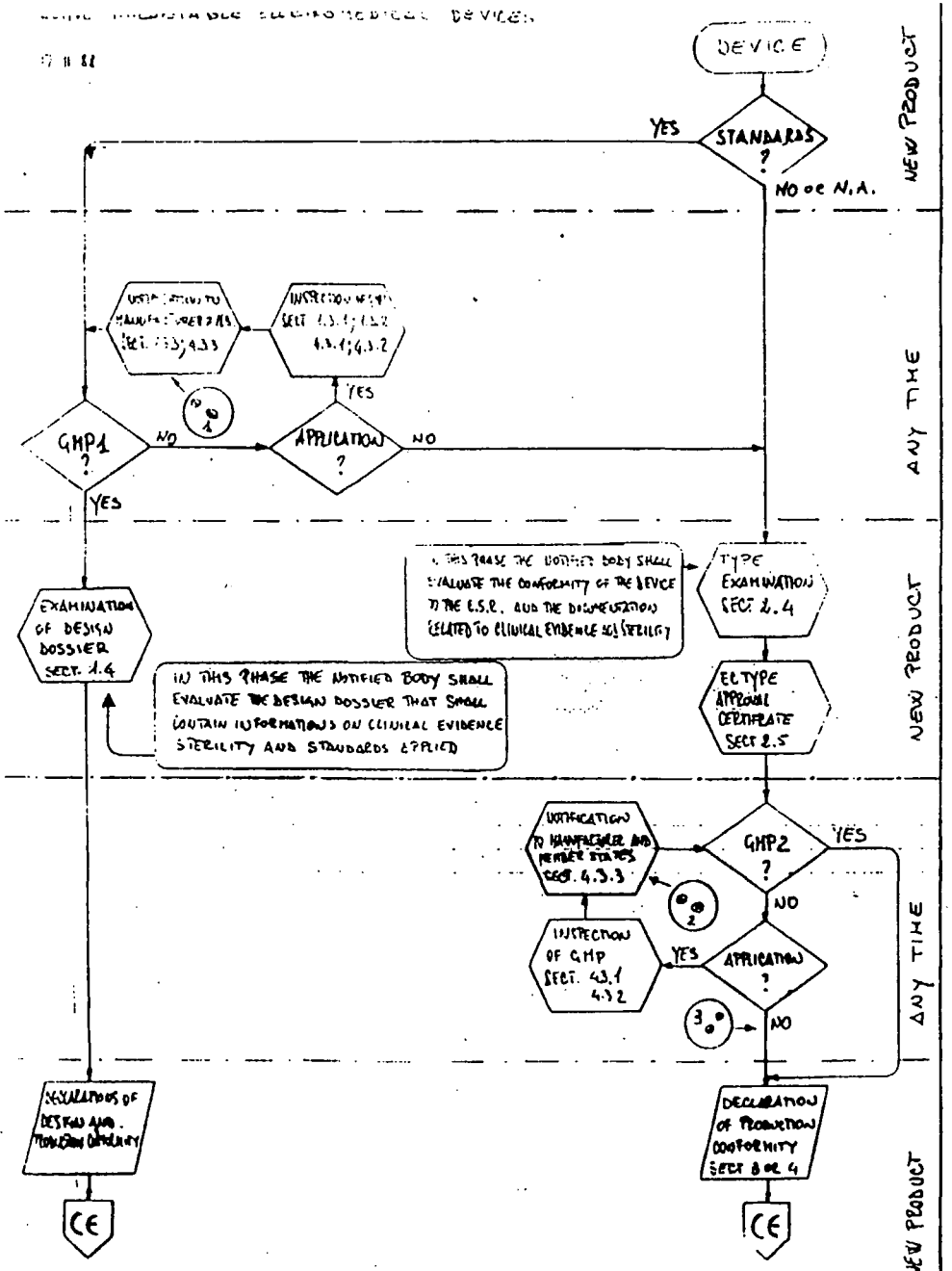
M

7. Attestation of conformity

The essential safety requirements to which implants must conform can be classified under three headings, namely sterility, clinical evaluation and technical safety. With regard to compliance with these three aspects, the Directive establishes three different strands which converge at the "design documents" stage and lead to the issue of a Community mark of conformity.

Technical safety may be evaluated on the basis of tests carried out on a prototype and evaluation will be facilitated if the design and construction of the equipment is in accordance with standards. The Directive therefore describes a set of procedures which are fairly representative of the certification procedures normally set out in Community directives.

Sterility will make it necessary to have rules and a strict oganization of the manufacturing process.



NOTIFIED BODY ACTIONS

MANUFACTURER ACTIONS

STANDARDS : HARMONIZED STANDARDS AS DESCRIBED IN ART. 5.1

GMP1 : QUALITY SYSTEM ACCORDING TO EN 29001, PROVISIONS ARE CONTAINED IN SECTIONS 1.3 AND 4.3 OF ANNEX II

GMP2 : QUALITY SYSTEM ACCORDING TO EN 29002, PROVISIONS ARE CONTAINED IN SECTION 4.3 OF ANNEX II

SECT.. : REFERENCE TO SECTIONS OF ANNEX II

APPLICATION : THE MANUFACTURER CAN CHOOSE WHETHER OR NOT TO APPLY FOR A GMP

CE : IS THE CEMARK THAT SHALL BE AFFIXED BY THE MANUFACTURER

(1) : EC SURVEILLANCE . SECT. 4.5 AND 4.4

(2) : EC SURVEILLANCE . SECT. 4.4

(3) : STATISTICAL CONTROL . SECT 3.3

Proposal for a

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on the approximation of the laws of the Member States relating to active implantable electromedical equipment

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,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas, in each Member State, active implantable electromedical devices used in human medicine must meet a high and clearly-defined level of safety both for the users of such equipment and for those receiving treatment by means of the equipment;

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

Whereas the national provision ensuring such safety level should be harmonized in order to guarantee the free market of active implantable electromedical devices without lowering existing and justified levels of safety in the Member States;

Whereas the regulations for active implantable electromedical devices can be confined to those provisions needed to satisfy the essential safety requirements: whereas because they are essential these requirements must replace corresponding national provisions;

Whereas, inspection procedures have to be provided, established on basis of mutual acceptance by the Member States in conformity with Community criteria,

HAS ADOPTED THIS DIRECTIVE :

CHAPTER I

Article 1

1. This Directive applies to active implantable electromedical devices.

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

- Medical device : any instrument, apparatus, implement, substance or other article (used singly or in combination) which is intended by the manufacturer for use in humans for :

  a. Contraception,
  b. Diagnosis, prevention, monitoring, treatment or alleviation of disease or injury,
  c. Investigation or modification of the anatomy or of a physiological process,

  which does not achieve its principal intended action by pharmacological means.
  Software packages which do not form part of an instrument, apparatus, implement or article are excluded from this definition;

- active implantable electromedical device : any medical device which is intended to be permanently implanted within the human body by a surgical operation, such a device using electricity from an implanted battery or an external source of power, together with non-interchangeable accessories (such as programmers, external power sources) and operating software;

- permanently implanted : implantation within the human body for purposes other than for short-term purposes.

Article 2

Member States shall take all necessary steps to ensure that devices referred to in Article 1(1), hereinafter referred to as "devices", may be placed on the market and implanted only if they do not impair patients' safety, when properly implanted, maintained and used according to their intended purposes.

Article 3

The devices referred to in Article 1(1) shall satisfy the essential safety requirements set out in Annex 1.

Article 4

1. Member States shall not impede the placing on the market, the free circulation and the implantation of devices bearing the CE-mark.

2. Member States shall not impede the placing on the market and the implantation of devices not bearing the CE-mark that are :

- intended for clinical evaluation according to the procedure of Article 8 (4);

- of a prototype nature intended for research and safety and effectiveness testing.

3. From the date of notification of this Directive, devices may continue, on a transitional basis for a period of 3 years, to be placed on the market subject to national provisions already in force on that date, provided that any such provisions are compatible with the requirements of the Treaty.

Article 5

1. Member States shall presume compliance with the essential safety requirements referred to in Annex 1 in respect of devices which are in conformity with :

a) the relevant national standards implementing the harmonized standards the references of which have been published in the Official Journal of the European Communities; Member States shall

publish the references of such national standards;

or with

b) the relevant national standards referred to in paragraph 2 insofar as, in the areas covered by such standards, no relevant harmonized standard exists.

2. Member States shall communicate to the Commission the texts of their national standards, as referred to in paragraph 1(b), which they regard as complying with the essential safety requirements referred to in Annex 1. The Commission shall forward such texts forthwith to the Member States. In accordance with the procedure provided for in Article 6(2), it shall notify the Member States of those national standards in respect of which there is a presumption of conformity with the essential safety requirements referred to in Annex 1.

Member States shall publish the reference numbers of those standards. The Commission shall also publish them in the Official Journal of the European Community.

Article 6

1. Where a Member State or the Commission considers that the harmonized standards referred to in Article 5(1) do not entirely meet the essential safety requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Standing Committee set up under Directive 83/189/EEC, hereinafter referred to as "the Committee", giving the reasons therefor. The Committee shall deliver an opinion without delay.

In the light of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw those standards from the publications referred to in Article 5(1)(a).

2. On receipt of the communication referred to in Article 5 (2), the Commission shall consult the Committee. After the Committee has given its opinion the Commission shall, within a given period, notify the Member States whether the national standard in question should or should not enjoy presumption of conformity and, if so, be subject to national publication of its references.

If the Commission or a Member State considers that a national standard no longer fulfils the conditions for presumption of conformity to the safety requirements, the Commission shall consult the Committee. In the light of the opinion of the Committee, it shall notify the Member States whether or not the standard in question should continue to enjoy presumption of conformity and in the latter case be withdrawn from the publications referred to in Article 5 (2).

Article 7

1. Where a Member State finds that devices bearing the CE-mark do not satisfy the essential safety requirements when properly implanted and used in accordance with their intended purpose, it shall take all appropriate measures to withdraw those products from the market or to prohibit or restrict their being placed on the market.

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

a) failure to meet the essential safety requirements referred to in Article 3, where the device does not meet the standards referred to in Article 5(1);

b) incorrect application of the standards referred to in Article 5(1);

c) shortcomings in the standards referred to in Article 5(1) themselves.

2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that any measure as referred to in paragraph 1 is justified, it shall immediately so inform the Member State that took the action and the other Member States. Where the decision referred to in paragraph 1 is attributed to shortcomings in the standards the Commission, after consulting the parties concerned, shall bring the matter before the Committee within two months if the Member State which has taken the measures intends to maintain them and shall initiate the procedures referred to in Article 6.

3. Where a device which does not comply bears the CE-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.

CHAPTER II

Conformity assessment

Article 8

1. Devices shall be subject to the EC type examination as described in Annex 2 section 2.

2. After having complied with paragraph 1, the manufacturer, or his authorized representative established within the Community, to be allowed to affix the CE-mark on his devices shall, at his own choice, either :

a) apply for EC declaration of production conformity as described in Annex 2, section 4

or

b) apply for EC declaration of production conformity as described in Annex 2, section 3.

3. Devices that are made according to standards referred to in Article 5 (1) can be subject, as an alternative to the provisions of paragraphs 1 and 2 and at manufacturer's choice, to the EC declaration of design conformity as described in Annex 2, section 1.

Such a declaration being integrated by the EC declaration of production conformity as described in Annex 2, section 4.

4. Standards referred to in Article 5(1) are of two different types : technical and clinical; for the latter, waiting for the production of an harmonized standard, devices shall be evaluated clinically according to the provisions of Annex 5.

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

Article 9

1. Member States shall notify to the other Member States and the Commission the bodies which they have designated for carrying out tasks pertaining to the procedures referred to in Article 8, the specific tasks for which each body has been designated, and the identification codes of the designated bodies.

The Commission shall publish the list of these notified bodies, together with the tasks for which they have been designated, in the Official Journal of the European Communities and shall ensure that the list is kept up to date.

2. Member States shall apply the minimum criteria, set out in Annex 4, for the designation of bodies. Bodies that satisfy the criteria fixed by the relevant harmonized standards shall be presumed to satisfy the criteria set out in Annex 4.

3. A Member State that has designated a body shall annul the designation if the body no longer meets the criteria for designation referred to in paragraph 2. It shall immediately inform the other Member States and the Commission accordingly and withdraw the notification.

CHAPTER III

CE-mark of conformity and inscriptions

Article 10

1. The CE-mark of conformity as referred to in Annex 3 shall be affixed to the device where practicable or on the package or on the accompanying documents in a clearly visible, easily legible and indelible form.

2. The affixing of marks which are likely to be confused with the CE-mark of conformity shall be prohibited.

Article 11

Where it is established that the CE-mark has been wrongly affixed to devices because :

- they do not conform to the relevant standards referred to in Article 5(1) ;

- they do not conform to an approved type

- they conform to an approved type which does not meet the essential requirements applicable to it

- the manufacturer has falled to fulfil his obligations under the relevant EC declaration of production conformity

the inspection body shall withdraw the EC design approval certificate or the EC quality systems approval certificate.

CHAPTER IV

Article 12

Any decision taken pursuant to this Directive and resulting in restrictions on the placing on the market and/or taking into service of a device shall state the exact grounds on which it is based. Such decision shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the laws in force in the Member State in question and of the time limits to which such remedies are subject.

Article 13

1. Before 1 July 1991, Member States shall adopt and publish the laws, regulations and administrative provisions necessary in order to comply with this Directive. They shall forthwith inform the Commission thereof.

   They shall apply such provisions from 1 January 1992.

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.

Article 14

This Directive is addressed to the Member States.

Done at Brussels

For the Council

The President

ANNEX 1

Essential safety requirements for active implantable electromedical devices.

1. Sterility

Patients shall be adequately protected against the risks caused by the use of non-sterile products.

2. Clinical evaluation

2.1. The clinical conditions of the patient shall not be worsened by the implantation of the device.

2.2. Side effects or any undesirable conditions introduced by the device shall not outweigh its positive effect.

3. Technical evaluation

3.1. Protection against misuse

The function of such devices shall be laid down in the instructions for use and on the labelling in order to ensure.

3.1.1. That physicians are fully aware of the potential and limitations of such devices.

3.1.2. That physicians have sufficient information to make a correct decision about utilization of the device.

3.1.3. That product parameters and packaging information shall be given in such a way that misinterpretations are minimized.

3.2. Protections against hazards arising from the device

Measures of a technical nature shall be taken in order to ensure:

3.2.1. That patients are adequately protected against risk of physical injury which might be caused by product design such as physical and dimensional features together with the biological characteristics of the materials used.

3.2.2. That patients are adequately protected against power supply depletion by means of a manufacturer's statement with respect to the end of life criteria.

3.2.3. That patients are adequately protected against the hazards related to the use of electricity such as :

a) poor insulation

b) excessive leakage currents for the intended use

c) poor protection of electrical circuits from the risk of contacts with body fluids

d) excess heat generated by the device.

3.2.4. Protection against hazards caused by the impossibility of carrying on systematic maintenance and calibration such as :

a) significant deterioration in performance features,

b) excessive increase of leakage currents,

c) degradation of the materials used,

d) ingress of body fluids or leakage of containers,

e) excessive increase of device-generated heat.

3.2.5. Protection against hazards which might be caused by environmental influences.

a) The device shall be designed and manufactured in such a way that mechanical stress which may occur during normal use will not irreversibly degrade its safety.

b) The device shall be manufactured and packed in such a way that it can resist, within the limits set by the manufacturer, to the environment conditions variations (temperature, humidity) that could occur either in normal use and during transport and storage, in such a way that its performance will not be irreversibly degraded, to such a degree that patient's safety is jeopardized.

c) Measures shall be adopted in order to reasonably protect the patient in which the device has been implanted, from the hazards arising from electromagnetic fields or from external electrical influences (defibrillators, high frequence surgical equipment, etc.).

ANNEX 2

Conformity assessment procedure

1. EC Declaration of design conformity

1.1 The EC declaration of design conformity is the process whereby the manufacturer who satisfies the obligations of paragraph 1.2 declares that the design of the type concerned satisfies the requirements of the directive that apply to it.

1.2. Obligations

1.2.1 The manufacturer shall have adequately implemented a quality system for design control that will ensure that design output will meet approved design requirements, and is subject to EC surveillance as specified in paragraph 1.5.

1.2.2 The manufacturer shall make only once the application for the whole quality system covering the provisions of this section and those of section 4 of this annex, with the exceptions of the provisions of paragraphe 1.4 , and when new technologies are introduced in the production process, together with a new product.

1.3 Quality system

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

The application shall include

- the quality system's documentation and all other relevant information
- an undertaking to carry out the obligations arising from the quality system as approved
- an undertaking to maintain the approved quality system to ensure its continuing suitability and effectiveness.

1.3.2 All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals, and records.

It shall contain in particular an adequate description of

- the quality objectives, and the organizational structure and responsibilities of management and their powers with regard to design quality
- the design control techniques, processes, and systematic actions that will be used
- the design verification techniques, processes, and systematic actions that will be used, and the frequency with which they will be used.
- the means to monitor the achievement of the required design quality and the effective operation of the quality system.

1.3.3 The notified body shall examine and evaluate the quality system to determine whether it satisfies the requirements referred to in paragraph 1.3.2. It shall presume compliance with these requirements in respect of quality systems that implement the design elements of the corresponding harmonized standard.

The notified body shall notify its decision to the manufacturer and inform the other notified bodies thereof. The notification to the manufacturer shall contain the conclusions of the examination and the reasoned assessment decision.

1.3.4 The manufacturer or his authorized representative established in the Community shall keep the notified body that has approved the quality system informed of any updating of the quality system in relation to changes brought about by, e.g., new design technologies and quality concepts.

1.3.5 A notified body that withdraws approval of a quality system shall so inform the other notified bodies, giving the reasons for the decision.

1.4 Design requirements

The manufacturer shall establish the design requirements of the type on the basis of the requirements of the directive that apply to it, and submit those to the notified body.

The notified body shall examine and evaluate the design requirements to determine whether they satisfy the relevant requirements of this directive. It shall notify its decision to the manufacturer and inform the other notified bodies thereof. The notification to the manufacturer shall contain the conclusions of the examination and the reasoned assessment decision.

The notified body shall also verify whether the clinical tests have been carried out according to the provisions of Article 8 paragraph 4.

1.5 EC surveillance

1.5.1 The purpose of EC surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

1.5.2 The manufacturer shall, upon request, provide all necessary information to the notified body, in particular

- the quality system documentation
- the approved design requirements
- the up to date quality records as foreseen by the quality system, such as results of analyses, calculations, tests, etc.

1.5.3 The notified body shall make sure that the manufacturer maintains and applies the quality system.
It shall provide a surveillance report to the manufacturer.

2. <u>EC type examination</u>

2.1 The EC type examination is that part of the procedure by which a notified body ascertains and certifies that a product, representative of the production envisaged, meets the provisions of the directive that apply to it.

2.2 The application for the type examination shall be lodged by the manufacturer or his authorized representative established within the Community with a single notified body.

The application shall include

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition
- a written declaration that the application has not been lodged with any other notified body
- the design documentation, as described in paragraph 2.3

The applicant shall place at the disposal of the notified body a product, representative of the production envisaged hereinafter called "type". The notified body may request further samples of the type if needed by the test programme.

A type may additionally cover product variants provided that any modification does not affect the level of safety and other performance requirements of the type.

2.3 The design documentation shall contain so far as relevant for assessment :

- a general description of the type
- conceptual designs and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding of the above including the operation of the products.
- 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 where the standards referred to in article 5 have not been applied
- results of design calculations made and of examinations etc.
- test reports
- a report on clinical tests according to the provisions of Article 8 paragraph 4.

2.4 The notified body shall,

2.4.1 examine the design document and verify that the type has been manufactured in conformity with the design documentation and identify the elements which have been designed in accordance with the relevant provisions of the standard and the essential requirements of the directive;

2.4.2 perform or have performed the appropriate examination and/or tests to check whether the solutions adopted by the manufacturer meet the essential requirements where the standards referred to in article 6 have not been applied;

2.4.3 perform or have performed the appropriate examinations and/or tests to check whether the relevant standards were effectively applied where the manufacturer has chosen to do so thereby assuring comformity with the essential requirements;

2.4.4 agree with the applicant the location where the examination and/or tests shall be carried out.

2.5 Where the type meets the provisions of the directive the notified body shall issue an EC type approval certificate to the applicant. The certificate shall contain the conclusions of the examination, conditions (if any) for its validity, and the necessary data for identification of the approved type and if relevant description of its functioning. The relevant technical elements such as drawings and schemes shall be annexed to the certificate.

2.6 The other notified bodies shall be informed forthwith of the issuing of the EC type approval certificate and its additions referred to in 2.8.2 on the said type. They may obtain a copy of the EC type approval certificate and its additions and on a reasoned request may obtain a copy of the annexes to the certificate and the reports on the examinations and tests carried out.

2.7 A notified body that refuses to issue or withdraws an EC type approval certificate shall so inform the Member State which notified this body and the other notified bodies giving the reasons for the decision.

2.8.1 The applicant shall keep the notified body that has issued the EC type approval certificate informed of any modification to the approved type.

2.8.2 Modifications to the approved type must receive additional approval from the notified body that issued the EC type approval certificate where such changes affect the safety of patients when properly implanted, maintained and used according to their intended purpose. This additional approval is given in the form of an addition to the original EC type approval certificate.

3. EC declaration of production conformity (type 1)

3.1 The EC declaration of production conformity (type 1) is that part of the procedure whereby the manufacturer declares that the products concerned are in conformity with the type as described in the EC type approval certificate and satisfy the requirements of this directive that apply to them. The manufacturer shall affix the CE-mark to each product and draw up a written declaration of conformity. The CE-mark shall be accompanied by the identification symbol of the notified body responsible for the random checks set out in paragraph 3.3.

3.2 The manufacturer shall take all measures necessary in order that the manufacturing process including final product inspection and testing shall ensure homogeneity of production and compliance of the products with the type as described in the EC type approval certificate and with the requirements of the directive that apply to them. A notified body, chosen by the manufacturer, shall carry out random checks on products as set out in either paragraph 3a or 3b below.

3.3 a) The products shall be subject to statistical control where applicable and shall therefore be grouped into identifiable lots consisting of units of a single model and manufactured under essentially the same conditions. A sample is to be drawn and inspected to determine conformity with the acceptability criteria. The operating characteristics are specified below. In those cases where a batch is rejected the notified body shall take the appropriate measures to prevent the putting on the market of that batch.

3.3 b) On site product checks shall be undertaken at random intervals of one year or less. A sample of the product shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to ensure their comformity with the relevant requirements of the directive. In those cases where one of the products under examination does not conform, the notified body shall take measures appropriate to the nature of the defect(s).

4. EC declaration of production conformity (type 2)

4.1 The EC declaration of production conformity (type 2) is the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 declares that the products concerned are in conformity with the type as described in the EC type approval certificate and satisfy the requirements of this directive that apply to them. The manufacturer shall affix the CE-mark to each product and draw up a written declaration of conformity. The CE-mark shall be accompanied by the identification symbol of the notified body responsible for EC surveillance.

4.2.1 The manufacturer shall have adequately implemented a quality system that will ensure compliance of the products with the type as described in the EC type approval certificate or in the EC declaration of design conformity and with the requirement(s) of this directive that apply to them. The manufacturer is subject to EC surveillance as specified in section 4 paragraph 4.

4.2.2 The manufacturer shall make only once the application for the quality system mentioned in this section, with the exception of the case when new technologies are introduced in the production process in view of a new product.

4.3 Quality system

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

The application shall include:

- all relevant information, in particular the quality system's documentation and the design documentation of the approved type

- an undertaking to carry out the obligations arising from the quality system as approved

- an undertaking to maintain the approved quality system to ensure its continuing suitability and effectiveness.

4.3.2. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall ensure a common understanding of the quality programmes, plans, manuals, and records.

It shall contain in particular an adequate description of

- the quality objectives, and the organizational structure and responsibilities of management and of their powers with regard to product quality

- the manufacturing processes, quality control and quality assurance, techniques and systematic actions that will be used

- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out

- the means to monitor the achievement of the required product quality and the effective operation of the quality system.

4.3.3. The notified body shall examine and evaluate the quality system to determine whether it satisfies the requirements referred to in section 3, paragraph 2. It shall presume comformity with these requirements in respect of quality systems that implement the corresponding harmonized standard.

It shall notify its decision to the manufacturer and inform the other notified bodies thereof. The notification to the manufacturer shall contain the conclusions of the examination and the reasoned assessment decision.

4.3.4 The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any updating of the quality system in relation to changes brought about by, e.g., new technologies and quality concepts.

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4.3.5 A notified body that withdraws approval of a quality system shall so inform the other notified bodies, giving the reasons for the decision.

4.4 EC surveillance

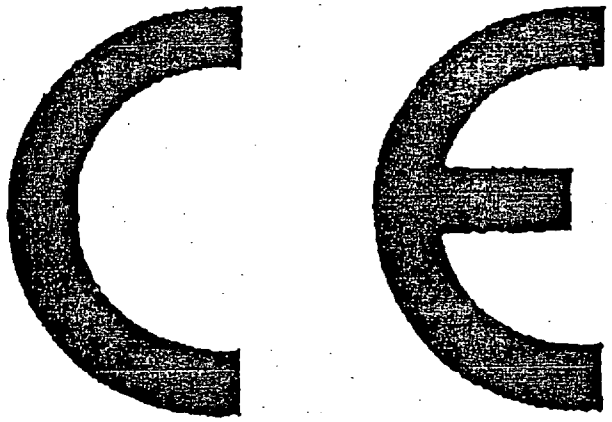
4.4.1 The purpose of EC surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.4.2 The manufacturer shall allow the notified body entrance for inspection purposes to the locations of manufacture, inspection and testing, and storage and shall provide it with all necessary information, in particular

- the quality system documentation
- the design documentation
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.4.3 The notified body shall make sure that the manufacturer maintains and applies the quality system and shall provide a surveillance report to the manufacturer.

ANNEX 3



Devices shall be identified by the manufacturer by means of type-, batch- or serial numbers.

ANNEX 4

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES WHEN APPOINTING INSPECTION BODIES

1. The notified body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of apparatus which they inspect, nor the authorized representative af any of those parties. They shall not become directly involved in the design, construction, marketing or maintenance of the apparatus, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer and the notified body.

2. The notified body and its staff must carry out the verification tests with the highest degree of professional integrity and technical competence 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 result of verifications.

3. The notified body must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it must also have access to the equipment required for special verification.

4. The staff responsible for inspection must have :

- sound technical and professional training,
- satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
- the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.

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

6. The notified body must take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.

7. The staff of the notified body is bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.

ANNEX 5

Clinical evaluation

Clinical evaluation can be checked by means of clinical tests performed according to the following points :

1. Clinical tests shall be performed in a recognized clinical environment specific for the pathologies that the device is intended to treat.

2. Clinical tests shall be performed under the responsability of a recognized consultant specialist in the relevant pathology.

3. The procedures utilized to perform clinical tests shall be consistent with the device under examination.

4. Methods to perform the tests shall be consistent with the device under examination.

5. All appropriate features involving safety of the device shall be examined.

FINANCIAL STATEMENT

regarding the proposal for a Council Directive on the approximation of the laws of the Member States relating to active implantable electromedical equipment (hereinafter referred to as implants).

1. Introduction

The proposal for a Directive on implants defines the essential safety requirements which they must satisfy. Article 5 of the proposal specifies that there should be a general reference, as a matter of priority, to European standards or, as a transitional measure, to national standards in so far as European standards do not exist. Equipment manufactured in accordance with these standards is deemed to conform to the essential requirements concerned in the Directive.

The Commission plans to help strengthen European standards by assigning to CEN and/or CENELEC the task of preparing the harmonized standards required in the implants sector in accordance with the general guidelines on cooperation between the Commission, CEN and CENELEC approved on 13 November 1984. This work will be carried out within the framework of mandates assigned to CEN and/or CENELEC pursuant to the framework contracts signed on 10 October 1985, which provide for financial support from the Commission.

The above mentioned work, which is of a limited duration, must be integrated within the general management framework of the Directive, which is a long-term project.

The figures given can only be summary estimates since European standardization is still at the planning stage.

2. Budget headings concerned

Article 775	:	Projects concerning the internal market
Item 7750	:	Harmonization of industrial and occupational legislation
	:	Multiannual project to strengthen the European standards bodies.

3. Legal basis

3.1. Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards(1).

3.2. Directive to be adopted by the Council providing for the alignment of the laws of the Member States relating to active implantable electromedical equipment.

4. Proposed classification

Non-compulsory expenditure.

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(1) OJ C 136, 4.6.1985.

5. Description and justification of the project.

5.1. Objectives

The projects planned should help in drawing up harmonized standards which meet the essential requirements of the Directive on implants and without which it would be very difficult to apply the Directive. The harmonized standards will also help to strengthen the competitiveness of European industry.

5.2. Persons concerned

In agreement with the Council Resolution of 7 May 1985, standardization is not the responsibility of the Commission, but that of the European standards bodies.

6. Type of expenditure and method of calculation

6.1. Type

It concerns mandates for the execution of the framework contract of 10 October 1985 between the Commission and CEN/CENELEC.

6.2. Calculation

The amount of finance for the services will be determined for each order in the light of the work assigned to the contractors.

It includes the expenditure incurred by the central departments of the European standards bodies in implementing the standards programmes assigned to them and a contribution to the expenditure incurred by the technical committees and working parties in carrying out the programmes. To this expenditure may be added specific expenditure in respect of experts assigned specific work in this context.

The expenditure is calculated on the basis of the "man/month" unit, which currently stands at 5.000 ECU.

The work of drawing up the harmonized standards will certainly have to continue beyond the first five years.

7. Financial implications for operating appropriations

7.1. Timetable of commitment and payment appropriations :

(Item 7750)

	CA (ECU)	PA (ECU)
1988	100.000	50.000
1989	100.000	150.000
1990	200.000	150.000
1991	100.000	100.000
1992	p.m.	50.000
	500.000	500.000

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7.2. Proportion financed from the Community budget

Since the parties involved in the standards work will in principle bear their own costs, the Community contribution to the funding of the project should not exceed 50 % of the total expenditure.

However, it should be noted that the Community contribution will be lower if the EFTA countries decide to take part.

8. Observations

None

9. Financial implications for staff and current administrative appropriations

9.1. Staff working exclusively on the project.

The project also includes management of the Directive on active implantable electromedical equipment, which will require the full-time participation of the Commission departments concerned.

From 1988 one A official will be needed for six months a year and one B official full-time.

9.2. + 9.3. Staff and current administrative appropriations

The appropriations required are estimated at 120.000 ECU a year.

COMPETITIVENESS AND EMPLOYMENT IMPACT STATEMENT

I. What is the main reason for introducing the measure ?

Active, implantable electromedical equipment, hereinafter referred to as implants, constitutes a high-technology sector which is rapidly developing and making a major contribution to the health and survival of a large number of people.

Within the Community, there are substantial differences between the national regulations in this field as regards clinical evaluation, technical requirements, the means of attestation of conformity and surveillance of manufacturing processes. The incompatibility of these laws and the need to repeat certain procedures slow down technical innovation and delay the marketing of equipment which represents a technological breakthrough and is able to save the lives of further categories of patients.

This disparity also hampers intra-Community trade as it introduces technical barriers to the free movement of goods within the Community and thus constitutes a barrier to the completion of the internal market.

The aim of this proposal for a Directive is to ensure the free placing on the market and commissioning of implants that meet the basic safety requirements of the Directive, which have to be duly attested.

II. Features of the businesses in question. In particular :

Are there many SMEs ?

Yes, although the exact member is difficult to determine due to the lock of precise information from the federations concerned.

III. What direct obligations does this measure impose on businesses ?

From the date of entry into force of this Directive, all the appliances covered will have to be designed, manufactured and equipped in such a way as to satisfy the requirements of the Directive.

IV. What indirect obligations are local authorities likely to impose on businesses ?

The Directive will be applied in each Member State following its transposition into national law.

V. Are there any special measures in respect of SMEs ?

No.

VI. What is the likely effect on ?

- the competitiveness of businesses ?

The placing on the market of implants which carry the EC mark of conformity and which are declared to conform to the Directive will be simplified and expedited, which will reduce the marketing costs of manufacturers, importers and retailers. It will no longer be possible to create any obstacles to the free movement of such implants within the internal market, which will increase the technological competitiveness of the businesses in this sector.

- employment ?

A reduction in marketing costs should generally increase the competitiveness of the Community businesses in this sector, which will probably have a favourable effect on the employment market.

VII. Have both sides of industry been consulted ?

The IAPM, which includes the manufacturers of active implantable electromedical equipment, and the medical users of such equipment have played an active part in the work of the group of experts which helped in drafting this proposal for a Directive.