COUNCIL DIRECTIVE

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

(84/539/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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

Having regard to the opinion of the European Parliament (2),

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

Whereas, in each Member State, electro-medical equipment used in human or veterinary medicine must meet a high and clearly-defined degree 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 degree of safety by mandatory specifications relating both to the technical safety regulations and the inspection procedures; whereas those specifications differ from one Member State to another;

Whereas these obstacles to the establishment and operation of the common market can be reduced or even eliminated if the same specifications are adopted by all the Member States, either in addition to or in place of their present legislation;

Whereas it is advisable in the first instance to harmonize at Community level one section of the equipment in question; whereas the most adequate form of harmonization is by reference to the standards drawn up by the European Committee for Electrotechnical Standardization (Cenelec);

Whereas, in order to ensure that the equipment complies with the harmonized standards, the manufacturer acknowledges his responsibility by a mark or declaration of conformity;

Whereas technical progress requires prompt adaptation of the technical specifications laid down by the Directives with respect to electro-medical equipment; whereas, in order to facilitate the implementation of the measures required, provision should be made for a procedure establishing close cooperation between the Member States and the Commission within the Committee on the Adaptation to Technical Progress of the Directives for Removing Technical Barriers to Trade in Electro-medical Equipment;

Whereas electro-medical equipment, although conforming to the requirements of this Directive, might endanger public safety and health; whereas a procedure should therefore be laid down to obviate this risk,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive shall apply to the electro-medical equipment listed in Annex II (hereinafter called 'equipment') which is intended, by its nature, for use in human or veterinary medicine.

Article 2

1. Member States may not, on grounds of safety relating to its manufacture, refuse, prohibit or restrict the sale, free movement or use for its intended purpose of the equipment referred to in Article 1 of this Directive where it conforms with the requirements of this Directive.

Annex I contains the technical requirements to which the equipment must conform.

(1) OJ No C 33, 12. 2. 1975, p. 5.
(2) OJ No C 76, 14. 3. 1975, p. 37.
(3) OJ No C 233, 17. 11. 1975, p. 39.

2. The conformity of equipment to the requirements of this Directive shall be attested by the manufacturer or by the importer, under the latter's responsibility, by the affixing of a mark which conforms to the specimen shown in Annex III or by a declaration which conforms to the specimen shown in Annex IV.

Article 3

Member States shall ensure that the services provided with the help of equipment meeting the requirements of this Directive are reimbursed on the same terms as the services provided with the help of equipment meeting the criteria required under the provisions in force within their territory as regards the authorized applications and minimum requirements for the equipment.

Article 4

The following shall be adopted in accordance with the procedure laid down in Article 6:

— any amendments to Annex I made necessary by the adaptation to technical progress of the harmonized standards by the relevant standards organization,

— any amendments to Annex I which are desirable because of adaptation to technical progress where the relevant standards organization has not made the corresponding amendments to the harmonized standard.

In the latter case, the amendments shall be notified to the competent standards organization.

Article 5

1. A Committee on the Adaptation to Technical Progress of the Directives for Removing Technical Barriers to Trade in Electro-medical Equipment (hereinafter called 'the Committee') is hereby set up; it shall consist of representatives of the Member States and shall be chaired by a Commission representative.

2. The Committee shall draw up its own rules of procedure.

Article 6

1. Where reference is made to the procedure laid down in this Article, the matter shall be referred to the Committee by its chairman, either on his own initiative or at the request of a representative of a Member State.

2. The Commission representative shall submit to the Committee a draft of the measures to be taken. The Committee shall give its opinion on that draft within a time limit set by the chairman having regard to the urgency of the matter. Opinions shall be delivered by a majority of 45 votes, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) Where the proposed measures are in accordance with the opinion of the Committee the Commission shall adopt them.

(b) Where the proposed measures 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 on the measures to be taken. The Council shall act by a qualified majority.

(c) If, within three months of the proposal being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 7

1. If a Member State determines, on the basis of a substantiated justification, that one or more appliances, although complying with the requirements of this Directive, represent a hazard to safety, it may provisionally prohibit the sale, free movement or use of the appliance or appliances on its territory or make it subject to special conditions. It shall immediately inform the other Member States and the Commission thereof, stating the grounds for its decision.

2. The Commission shall, within six weeks, consult the Member States concerned, following which it shall deliver its opinion without delay and take the appropriate steps.

3. If the Commission is of the opinion that technical adaptations to the Directive are necessary, such adaptations shall be adopted by either the Commission or the Council in accordance with the procedure laid down in Article 6. In that case, the Member State which has adopted the safeguard measures may maintain them until the entry into force of the adaptations.

Article 8

1. Member States shall take all appropriate measures to ensure that the marks and declaration of conformity referred to in Article 2 are issued by the manufacturer

or the importer only under the conditions laid down in the Directive.

2. Member States shall make all necessary arrangements to ensure adequate surveillance of the manufacture of the equipment.

Article 9

Member States shall take all appropriate measures to prevent the use on equipment of marks or markings which might be confused with the EEC mark described in Annex III.

Article 10

1. Member States shall bring into force the measures necessary to comply with this Directive within 24 months of its notification and shall forthwith inform the Commission thereof (1).

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

Article 11

This Directive is addressed to the Member States.

Done at Brussels, 17 September 1984.

For the Council

The President

P. BARRY

(1) This Directive was notified to the Member States on 26 September 1984.

ANNEX I

The technical requirements to which the equipment referred to in Article 1 must conform are the following:

Harmonization document of the European Committee for Electrotechnical Standardization (Cenelec) HD 395-1: General Requirements (1979 edition — document based on IEC No 601-1 of the International Electrotechnical Commission); this standard being applicable subject to the following amendments:

In the case of the equipment referred to in 2.2.1.1 of Annex II, the requirements of HD 395-1 are amended as follows:

Sub-clause 14.6 (b):	The equipment shall be minimally of type BF;
Sub-clause 19.3:	Patient Auxiliary Current:
	Normal condition — 1 mA
	Single fault condition — 5 mA.

ANNEX II

LIST OF EQUIPMENT REFERRED TO IN ARTICLE 1

1. DIAGNOSTIC EQUIPMENT

(excluding equipment subject to defibrillator discharge protection)

1.1. **Equipment for the procurement of information from a living being without the influence of an external source.**

1.1.1. *Equipment for the procurement of biopotentials.*

1. Equipment and corresponding accessories for diagnostic or monitoring purposes to study or monitor electrical activity or electrical characteristics of living beings:
   - — electroencephalographs and electrocorticographs,
   - — electromyographs,
   - — electroretinographs,
   - — electronystagmographs.

2. Equipment and corresponding accessories.

1.1.2. *Equipment for the procurement of other parameters.*

1. Equipment and corresponding accessories to study the infra-red radiation produced by living organisms for diagnostic purposes:
   - — thermoscanners,
   - — thermographs,
   - — radiation thermometers.

2. Equipment and corresponding accessories to study acoustic activity or sensitivity of living beings:
   - — electronic stethoscopes,
   - — phonocardioscopes and phonocardiographs only where not intended for cardiovascular interventions,
   - — audiometers,
   - — audiophones.

3. Equipment and corresponding accessories:
   - — ballistocardiographs,
   - — electronic thermometers only where intended for cardiovascular interventions.

1.2. **Equipment for the procurement of information from a living being under the influence of an external source.**

1.2.1. *Equipment using an electronic source.*

Equipment and corresponding accessories which apply directly electrical currents to living organisms:

- — equipment for the measurement of skin resistance,
- — equipment for pulmonary or vascular impedance rheography.

1.2.2. *Equipment using another source.*

1. Equipment and corresponding accessories for ophthalmological diagnosis:

   — equipment for illumination of the eye: slit lamps, eye mirrors, spectral light sources, ophthalmoscopes,

   — equipment for viewing, imaging and measurement of the eye: ophthalmometers, refractometers, tonometers, photometers, retinoscopes, cornea-microscopes,

   — ophthalmological diagnostic units consisting of ophthalmological equipment as mentioned above combined with necessary auxiliary devices: stands, columns, chairs.

2. Equipment and corresponding accessories intended to support visibility by monocular or binocular enlargement for diagnostic purposes and to be used for viewing surgical procedures (excluding high-frequency surgical equipment):

   — surgical microscopes,

   — colposcopes,

   — otoscopes,

   — dermatoscopes.

3. Equipment and corresponding accessories intended for local illumination of areas to be examined or treated:

   — head-lamps,

   — illuminated head-mirrors,

   — fluorescent hand-lamps,

   — mouth-lamps.

2. THERAPEUTIC EQUIPMENT

2.1. **Specific therapeutic equipment.**

2.1.1. *Equipment using electric energy.*

1. Equipment and corresponding accessories which produce electrically charged or ionized air, vapours or mists; charging or ionization may be achieved by:

   — high voltage,

   — electron emission from hot metal.

2.1.2. *Equipment applying other forms of energy.*

1. Equipment and corresponding accessories which produce certain mechanical effects in medicine:

   — vibrators,

   — equipment for pressurized water-massage,

   — equipment for extracorporal cardiac massage.

2. Equipment and corresponding accessories which produce hot air, steam or vapours for medical therapeutic purposes:

   — equipment in which solid or liquid material is evaporated by heating or mechanical means for inhalation purposes,

   — hot-air baths.

   This section does not include ultrasonic equipment.

2.2. **Electro-surgical equipment.**

2.2.1. *Equipment using electric energy.*

1. Equipment and corresponding accessories using low-frequency electric energy to produce heat for electrocautery:
   - — equipment for electrocautery,
   - — parts of combined medical electrical equipment intended for electrocautery.

2.2.2. *Equipment using other forms of energy.*

1. Equipment and corresponding accessories for ophthalmological therapeutic purposes:
   - — equipment for treatment of the eye,
   - — eye magnets.
2. Equipment and corresponding accessories.
3. Equipment and corresponding accessories which produce certain mechanical effects in medicine:
   - — drilling, sawing and polishing equipment for dentistry or surgery,
   - — water-driven equipment.

2.3. **Equipment for the support or replacement of body functions**

(excluding implanted cardiac stimulators and other implanted devices).

2.3.1. *Equipment for support or replacement by other means.*

1. Equipment and corresponding accessories intended to support or replace certain body functions:
   - — artificial limbs,
   - — aids for the paralyzed,
   - — artificial speech equipment.
2. Equipment and corresponding accessories intended to assist human sensors:
   - — aids for the blind.

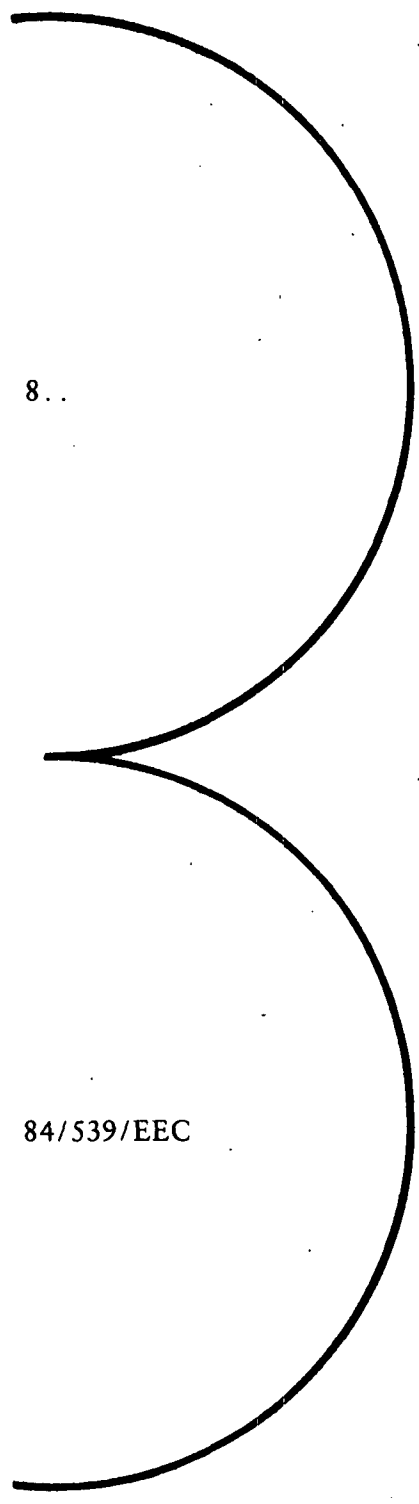
3. OTHER EQUIPMENT

Equipment and accessories for handling and positioning of the patient for surgical or dental purposes:

- — operating tables,
- — operating chairs,
- — operating units,
- — dental chairs,
- — dental units.

ANNEX III

SPECIMEN MARK OF CONFORMITY AFFIXED BY THE MANUFACTURER



equipment manufactured in 198..

in conformity with Directive 84/539/EEC

ANNEX IV

SPECIMEN DECLARATION OF CONFORMITY

Application of Council Directive 84/539/EEC of 17 September 1984

Manufacturer's name .....

Manufacturer's address .....

Name of equipment .....

Type No, Model No, or Reference No .....

Serial No .....

Year of manufacture .....

I, the undersigned, hereby declare that the equipment specified above conforms to Directive 84/539/EEC.

Place ....
(Signature)

Date ....
(Full name)

.....
(Position)

(To be completed and signed by a person responsible for the undertaking named in the Declaration)