L.N. 90 of 2002

PRODUCT SAFETY ACT (ACT NO. V OF 2001)

Electro-Medical Equipment Used in Veterinary Medicine Regulations, 2002

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, 2001, the Minister for Economic Services, on the advice of the Malta Standards Authority, has made the following regulations:-

Citation and commencement

1.1. The title of these regulations is the Electro-Medical Equipment Used In Veterinary Medicine Regulations, 2002.

1.2. These regulations shall become operative on the 1st July, 2002:

Provided that the requirements to provide information to the European Commission referred to in regulation 7.5 of these regulations shall come into force on such date as the Minister responsible for Consumer Affairs, after consultation with the Malta Standards Authority, may prescribe.

Scope

2.1. These regulations shall apply to electro-medical equipment listed in Annex II of the Directive, which is set out in Schedule II hereto, which is intended, by its nature, for use in veterinary medicine;

2.1.1. "Electro-medical equipment" shall hereinafter be referred to as "equipment".

Definitions

3.1.1. "The Directive" means Council Directive 84/539/EEC[1] on the approximation of the laws of the Member States relating to electro-medical equipment used in human or veterinary medicine, as amended by Directive 93/42/EEC as implemented in Malta through L.N. 67 of 2001: The Medical Devices Regulations, 2001[2].

3.1.2. "OJ" means the Official Journal of the European Communities.

3.1.3. "Manufacturer" means the person who is primarily responsible for the design and construction of the equipment so that it complies with the requirements of these regulations.

3.1.4. "Local authorised representative" means any person (or organisation) established in Malta who has been appointed by the manufacturer to act on his behalf in carrying out certain tasks required by these regulations.

3.1.5. "Importer" means any person who places equipment from a foreign country on to the Maltese market so that he supplies such equipment on the first occasion that it is supplied in Malta.

3.1.6. "Person who supplies equipment" means wholesalers, distributors, retailers etc..

3.1.7. "Supply" includes offering to supply, agreeing to supply, exposing for supply and possessing for supply, and cognate expressions shall be construed accordingly.

3.1.8. "Responsible person" in relation to equipment means:

3.1.8.1. the manufacturer thereof;

3.1.8.2. the manufacturer's local authorised representative; or

3.1.8.3. where the manufacturer is not established in Malta and he has not appointed a local authorised representative, the person who places the equipment on the local market.

3.1.9. "Placing on the market" means importation, wholesale, retail, sale and distribution free of charge.

Applicability

4.1. The provisions of these regulations are applicable to all imported equipment as well as to those manufactured for the local market.

4.1.1. No person may construct, import, place on the market or put into service any equipment which does not comply with the provisions of these regulations.

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[1] OJ No. L 300,19-11-84, p.179

[2] Gazette No. 17,078 of 30th March 2001

General requirements

5.1. If the appliance is at the same time a medical device within the meaning of Directive 93/42/EEC and if it satisfies the essential requirements laid down therein for that device, the device shall be deemed to be in conformity with the requirements of these regulations.

5.2. Annex I of the Directive, which is set out in Schedule I hereto, contains the technical requirements to which the equipment must conform.

5.3. All appropriate measures shall be taken to encourage the local authorities responsible for implementing these regulations to cooperate with each other and provide each other with information in order to assist the functioning of these regulations and to make all necessary arrangements to ensure adequate surveillance of the manufacture of the equipment.

Free movement

6.1. The sale, free movement or use for its intended purpose of the equipment referred to in regulation 2.1 of these regulations where it conforms with the requirements of these regulations may not, on grounds of safety relating to its manufacture be refused, prohibited or restricted.

Withdrawal and prohibition from market

7.1. If the Director of Consumer Affairs notes, on the basis of a substantial justification, that one or more appliances, although complying with the requirements of these regulations, represent a hazard to safety, it may provisionally prohibit the free movement or use of the appliance or appliances in Malta or subject it or them to special conditions.

7.1.1. Such a decision shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in Malta and of the time limits to which such remedies are subject.

7.1.2. The Director of Consumer Affairs shall immediately inform the Consumer and Industrial Goods Directorate[3] of the Malta Standards Authority, stating the grounds for its decision.

7.5. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission and the other Member States of any measures taken in pursuance of regulation 7.1 of these regulations.

Attestation of Conformity

8.1. The conformity of equipment to the requirements of these regulations 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 of the Directive, which is

set out in Schedule III hereto, or by a declaration which conforms to the specimen shown in Annex IV of the Directive, which is set out in Schedule IV to these regulations.

8.2. All appropriate measures shall be taken to prevent the use on equipment of marks or markings which might be confused with the EEC mark described.

Adaptation of the regulations to technical progress

9.1. The following shall be adopted in accordance with the procedure laid down in Article 6 of the Directive:

9.1.1. Any amendments to Annex 1 of the Directive, which is set out in Schedule I hereto, made necessary by the adaptation to technical progress of the harmonised standards by the relevant standards organisation,

9.1.2. Any amendments to Annex 1 of the Directive, which is set out in Schedule I hereto, which are desirable because of adaptation to technical progress where the relevant standards organisation has not made the corresponding amendments to the harmonised standard. In this case any amendments shall be notified to the competent standards organisation.

[4] L.N. 213 of 2000 – Malta Standards Authority (Establishment of directorates) Order, 2000, published in the *Government Gazette* No 17,002 of 20th October, 2000.

Schedule I

Based on Annex I of the Directive

The technical requirements to which the equipment referred to in regulation 2.1 of these regulations must conform are the following:

Harmonisation document of the European Committee for Electrotechnical Standardisation (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 point 2.2.1.1 of Annex II of the Directive, which is set out in Schedule II hereto, 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

Schedule II

Based on Annex II of the Directive

LIST OF EQUIPMENT REFERRED TO IN REGULATION 2.1

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 ophthalmolgical 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-micrsocopes,

– ophthalmological diagnostic units consisting of ophthalmological equipment as mentioned above combined with necessary auxiliary devicesĠ stands, columns, chairs.

2. Equipment and corresponding accessories intended to support visibility by monocular or binocular enlargements 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 ionised air, vapours or mists; charging or ionisation 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-message,

– equipment for extracorporal cardiac message.

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 ophthalmoligical 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 paralysed,

– 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,

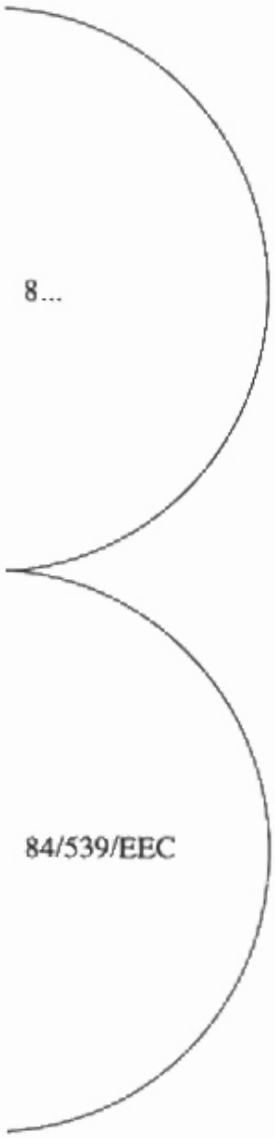
– dental chairs,

– dental units.

Schedule III

Based on Annex III of the Directive

SPECIMEN MARK OF CONFORMITY AFFIXED BY THE MANUFACTURER



8... equipment manufactured in 198..

84/539/EEC in conformity with Directive 84/539/EEC

Schedule IV

Based on Annex IV of the Directive

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. .....

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)

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