

1988 No. 1586

**TRADE DESCRIPTIONS**

**The Electro-medical Equipment (EEC Requirements)  
Regulations 1988**

<i>Made - - - -</i>	<i>9th September 1988</i>
<i>Laid before Parliament</i>	<i>20th September 1988</i>
<i>Coming into force</i>	<i>11th October 1988</i>

The Secretary of State, being a Minister designated(a) for the purposes of section 2(2) of the European Communities Act 1972(b) in relation to the sale, free movement or use of electro-medical equipment which conforms to prescribed standards and the reimbursement in respect of services provided with the help of such equipment, in the exercise of powers conferred by that section and of all other powers enabling him in that behalf, hereby makes the following Regulations:

**Citation and commencement**

1. These Regulations may be cited as the Electro-medical Equipment (EEC Requirements) Regulations 1988 and shall come into force on 11th October 1988.

**Interpretation**

2. In these Regulations—

“the Act of 1968” means the Trade Descriptions Act 1968(c);

“the Directive” means Council Directive 84/539/EEC on the approximation of the laws of the member States relating to electro-medical equipment used in human or veterinary medicine(d);

“declaration” means a declaration which conforms with the specimen declaration contained in Annex IV to the Directive;

“electro-medical equipment” means electro-medical equipment listed in Annex II to the Directive which is intended, by its nature, for use in human or veterinary medicine;

“the reversed epsilon” means a mark which conforms with the specimen mark contained in Annex III to the Directive;

“supply” has the same meaning as in section 46 of the Consumer Protection Act 1987(e) and includes offering to supply, agreeing to supply, exposing for supply and possessing for supply.

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(a) S.I. 1986/947.

(b) 1972 c.68; section 2 is subject to Schedule 2 to the Act and is to be read, as regards England and Wales, with section 32(7) and (9) of the Magistrates' Courts Act 1980 (c.43) and S.I. 1984/447, as regards Scotland, with section 289 B(4) and (6) of the Criminal Procedure (Scotland) Act 1975 (c.21), as inserted by paragraph 5 of Schedule 11 to the Criminal Law Act 1977 (c.45) and amended by section 55(2) of the Criminal Justice Act 1982 (c.48) and S.I. 1984/526 and, as regards Northern Ireland, with S.I. 1984/703 (N.I. 3) and S.R. (N.I.) 1984 No. 253.

(c) 1968 c.29.

(d) O.J. No. L 300, 19.11.84, p.179.

(e) 1987 c.43.

### Marking

3. Where any person supplies electro-medical equipment which is marked with the reversed epsilon (or with a mark so closely resembling it as to be likely to be taken to be the reversed epsilon) or to which a declaration has been applied but that equipment does not comply with the technical requirements contained in Annex I to the Directive that person shall be guilty of an offence.

### Application of the Trade Descriptions Act 1968

4.—(1) The following provisions of the Act of 1968 shall (with necessary modifications) apply in relation to an offence under these Regulations as they apply in relation to an offence under that Act (modified where appropriate in relation to Northern Ireland by section 40(1) of that Act(a)), that is to say sections 18(b), 19(c), 20, and 24.

(2) The following provisions of the Act of 1968 shall (with necessary modifications) apply in relation to the enforcement of these Regulations as they apply in relation to the enforcement of that Act (modified where appropriate in relation to Northern Ireland by section 40(1) of that Act), that is to say sections 26(d), 27, 28(e), 29(f) and 30(1).

(3) Section 33 of the Act of 1968 (modified in relation to Northern Ireland by section 40(1) of that Act) shall apply in relation to compensation for goods seized and detained under these Regulations as it applies to compensation for goods seized and detained under that Act.

### Enforcement of health and safety legislation

5.—(1) In any proceedings against a person for an offence under any of the relevant statutory provisions (as defined by section 53(1) of the Health and Safety at Work etc Act 1974(g) or, as the case may be, article 2(2) of the Health and Safety at Work (Northern Ireland) Order 1978(h)) which imposes requirements on grounds of safety relating to the manufacture of electro-medical equipment for use at work, it shall be a defence for that person to show that that equipment conforms with the requirements of the Directive.

(2) Where an improvement notice or prohibition notice has been served on any person pursuant to section 21 or, as the case may be, section 22 of the Health and Safety at Work etc Act 1974, or articles 23 or 24 of the Health and Safety at Work (Northern Ireland) Order 1978, if the person upon whom the notice was served appeals to an industrial tribunal pursuant to section 24 of the said Act or article 26 of the said Order and shows that the notice refers to grounds of safety relating to the manufacture of electro-medical equipment for use at work which conforms with the requirements of the Directive, the tribunal shall cancel the notice.

*K. Clarke*

9th September 1988

One of Her Majesty's Principal Secretaries of State

(a) Section 40(1) was amended by the Magistrates' Courts Act 1980 (c.43), section 154 and Schedule 7, paragraph 74, by S.I. 1981/1675 (N.I. 26), article 170(2) and Schedule 6, Part I, paragraph 13 and by S.I. 1980/704 (N.I. 6), article 12 and Schedule 1, Part II, paragraph 43.

(b) Section 18 was amended by the Magistrates' Courts Act 1980, section 32(2).

(c) Section 19 was amended by the Magistrates' Courts Act 1980, section 154 and Schedule 7, paragraph 75.

(d) Section 26 was amended by the Weights and Measures Act 1985 (c.72), sections 96(1) and 98(1), Schedule 11, paragraph 18(2) and Schedule 13, Part I; and by the Local Government, Planning and Land Act 1980 (c.65), sections 1(4) and 194, Schedule 4, paragraph 10(a) and Schedule 34, Part IV.

(e) Section 28 was amended by the Consumer Credit Act 1974 (c.39), section 192(3)(a) and Schedule 4, Part I, paragraph 28.

(f) Section 29 was amended by the Criminal Justice Act 1982 (c.48), sections 38 and 46.

(g) 1974 c.37.

(h) S.I. 1978/1039 (N.I. 9).

## **EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations implement Council Directive No. 84/539/EEC relating to electro-medical equipment which is intended, by its nature, for use in human or veterinary medicine.

Regulation 3 makes it an offence to apply the reversed epsilon mark or the declaration described in the Directive to electro-medical equipment which does not conform with the requirements of the Directive.

Regulation 4 applies provisions of the Trade Descriptions Act 1968 to that offence and to the enforcement of, and compensation for goods seized under, these Regulations.

Regulation 5 provides defences where certain proceedings are brought under the Health and Safety at Work etc Act 1974 or the Health and Safety at Work (Northern Ireland) Order 1978 in respect of the use or intended use at work of electro-medical equipment which conforms with the requirements of the Directive.