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STATUTORY INSTRUMENTS

1993 No. 2360

WEIGHTS AND MEASURES

The Clinical Thermometers (EEC Requirements) Regulations 1993

<i>Made</i>	- - - -	<i>29th September 1993</i>
<i>Laid before Parliament</i>		<i>30th September 1993</i>
<i>Coming into force</i>	- -	<i>21st October 1993</i>

The Secretary of State, being a Minister designated⁽¹⁾ for the purposes of section 2(2) of the European Communities Act 1972⁽²⁾ in relation to the regulation of specifications, construction, placing on the market and use of equipment intended for weighing, measuring or testing or for purposes ancillary thereto, in exercise of the powers conferred on her by that section and of all her other enabling powers, hereby makes the following Regulations:

PART I GENERAL

Citation and commencement

1. These Regulations may be cited as the Clinical Thermometers (EEC Requirements) Regulations 1993 and shall come into force on 21st October 1993.

Interpretation

2.—(1) In these Regulations except where the context otherwise requires—
“approved body” means a body approved by the Secretary of State under regulation 6;

(1) S.I. 1975/427.

(2) 1972 c. 68; section 2 is subject to Schedule 2 to that 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(F) and 289(G) of the Criminal Procedure (Scotland) Act 1975 (c. 21), as inserted by section 54 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. 1984 No. 253.

“clinical thermometer” means a thermometer to which these Regulations apply in accordance with regulation 3;

“the Directive” means Council Directive No. [76/764/EEC](#) on the approximation of the laws of the member States on clinical mercury–in–glass, maximum reading thermometers⁽³⁾, as amended by Council Directive No. [83/128/EEC](#)⁽⁴⁾ and Commission Directive No. [84/414/EEC](#)⁽⁵⁾;

“inspector” means a person authorised in writing by the Secretary of State to be an inspector for the purposes of these Regulations;

“the 1988 Regulations” means the Measuring Instruments (EEC Requirements) Regulations 1988⁽⁶⁾;

(2) In these Regulations, unless the context otherwise requires, any reference to a numbered regulation is a reference to the regulation bearing that number and any reference in a regulation to a numbered paragraph is a reference to the paragraph of that regulation bearing that number.

Application of Regulations

3. These Regulations apply to clinical mercury–in–glass, maximum reading thermo– meters designed to measure the internal temperature of humans or animals.

Pattern approval and initial verification: the EEC signs and marks

4.—(1) The EEC signs and marks referred to in these Regulations are the following signs and marks—

- (a) the sign of EEC pattern approval described in paragraph 1 of Schedule 1 to the 1988 Regulations or the alternative sign in paragraph 1 of the Schedule to these Regulations;
- (b) the sign of EEC limited pattern approval described in paragraph 2 of Schedule 1 to the 1988 Regulations or the alternative sign in paragraph 2 of the Schedule to these Regulations;
- (c) the mark of EEC initial verification described in paragraph 5 of Schedule 1 to the 1988 Regulations or the alternative mark in paragraph 3 of the Schedule to these Regulations.

(2) In these Regulations, references to the United Kingdom version of a sign or mark referred to in paragraph (1) are references to the sign or mark appropriate, in accordance with the provisions of Schedule 1 to the 1988 Regulations or the Schedule to these Regulations (as the case may be), for an EEC pattern approval granted, or (as the case may be) an EEC initial verification carried out, in the United Kingdom.

Free movement of clinical thermometers which bear sign of EEC pattern approval and mark of EEC initial verification

5. Subject to regulation 12 (temporary prohibition of sale or use) any rule of law, statutory or otherwise, which prohibits or restricts the sale or entry into use of clinical thermometers shall not apply to any thermometer which bears the sign of EEC pattern approval and the mark of EEC initial verification.

Approval of bodies

6.—(1) On application made by the body, the Secretary of State may approve one or more bodies of persons—

(3) O.J. No. L262, 27.9.1976, p.139.

(4) O.J. No. L91, 9.4.1983, p.29.

(5) O.J. No. L228, 25.8.1984, p.25.

(6) S.I. [1988/186](#), amended by S.I. [1988/1128](#) and [1992/1579](#).

- (a) to consider applications for EEC pattern approval, to conduct any examination for EEC pattern approval and to grant if appropriate, a certificate of EEC pattern approval in respect of clinical thermometers; and
 - (b) to carry out EEC initial verification and to affix the EEC mark of initial verification in respect of clinical thermometers.
- (2) Any such approval—
- (a) may be given for an unlimited period, or for a specified period, or for specified purposes; and
 - (b) may be given subject to conditions (including conditions which are to apply upon or following withdrawal of the approval).
- (3) The Secretary of State shall withdraw an approval if the body so requests and may withdraw an approval if the body ceases to comply with any such conditions.
- (4) In a case where the Secretary of State—
- (a) refuses an application for approval under paragraph (1) above or imposes any condition more onerous than any of those proposed by the body or imposes any condition at all when the body proposed none; or
 - (b) withdraws an approval under paragraph (3) above,
- he shall inform the body of the grounds for the refusal, imposition of that condition or withdrawal of approval, as the case may be.
- (5) If for any reason an approved body ceases to be an approved body under this regulation, the Secretary of State may designate another approved body to take over its functions in respect of such cases as he may specify.
- (6) The approved body may charge a fee in accordance with paragraphs (7), (8) and (9) for anything done in, or in connection with, performing a function under these Regulations.
- (7) Except as provided by paragraph (8) the fee charged in respect of anything done shall not exceed an amount which reasonably represents the cost incurred, or to be incurred in doing it.
- (8) Where the approved body is a body the activities of which are carried on for profit, the fee for doing anything may include an amount representing a profit which is reasonable in the circumstances, having regard to—
- (a) the character and extent of the work done or to be done by the approved body; and
 - (b) the commercial rate normally charged in respect of profit for that work or similar work.
- (9) The approved body may require payment of a fee or a reasonable estimate of the fee, in advance of carrying out the work in respect of which the fee is payable and as a condition of doing that work.

PART II

EEC PATTERN APPROVAL AND INITIAL VERIFICATION IN THE UNITED KINGDOM

EEC pattern approval

7. Regulation 8 to 11 of the 1988 Regulations (which contain provisions with respect to the grant, extension and revocation of EEC pattern approval), and Schedule 2 to those Regulations (which regulates the conduct in the United Kingdom of EEC pattern approval), shall apply in relation to the pattern approval of clinical thermometers to which these Regulations apply as they

apply in relation to the pattern approval of instruments to which those Regulations apply as if in regulation 8 to 11 of, and Schedule 2 to, the 1988 Regulations for the words “Secretary of State” wherever they appear there were substituted the words “the approved body” and for the words “the relevant Directive” wherever they appear there were substituted the words “Council Directive No. 76/764/EEC on the approximation of the laws of the member States on clinical mercury-in-glass, maximum reading, thermometers, as amended by Council Directive No. 83/128/EEC and Commission Directive No. 84/414/EEC”.

Application of signs of EEC pattern approval

8.—(1) Where an EEC pattern approval (whether granted under these Regulations or by any member State other than the United Kingdom) is in force in respect of a pattern of clinical thermometer, the manufacturer shall cause one or other of the two signs of EEC pattern approval, or where the pattern approval is limited approval, one or other of the two signs of EEC limited pattern approval, to be affixed to clinical thermometers conforming to the approved pattern.

(2) Any sign affixed in accordance with this regulation shall be affixed at a visible point and shall be legible and indelible.

EEC initial verification

9.—(1) An application for consideration of any clinical thermometer for EEC initial verification shall be made to an approved body together with such information as the approved body may reasonably require for the purposes of determining the application

(2) The approved body shall determine whether an EEC pattern approval is in force in respect of the clinical thermometer, and, if so, whether it conforms to the approved pattern and to the requirements of the Directive.

(3) Where the approved body is satisfied—

- (a) that the clinical thermometer conforms to the requirements of the Directive; and
- (b) that an EEC pattern approval is in force in respect of the clinical thermometer and that it conforms to the approved pattern,

the approved body shall cause to be affixed to it one or other of the two United Kingdom marks of EEC initial verification.

(4) If the approved body refuses to cause any mark of EEC initial verification to be affixed it shall give to the applicant a statement in writing of its reasons for the refusal.

PART III

SUPPLEMENTARY PROVISIONS

Limitation of number of clinical thermometers which may be submitted for EEC initial verification

10. Where an EEC limited pattern approval is subject to a condition limiting the number of clinical thermometers which may be submitted for initial verification by reference to the pattern in question, any person who makes an application, or causes or permits the making of an application, which if granted would contravene the condition, shall be guilty of an offence unless it is shown that he did not know, and had no reason to believe, that it would or might contravene the condition.

Use for trade of clinical thermometers where EEC pattern approval has been revoked or has not been extended

11. –

(1) Where pattern approval for any clinical thermometer ceases to apply by reason of it having been revoked or not extended, or any person who, knowing that the pattern approval has ceased to apply, uses for trade or has in his possession for such use or causes or permits any other person to use a clinical thermometer of the pattern in question bearing any EEC sign or mark related to the pattern approval, or disposes of any such clinical thermometer to any other person in a state in which it could be so used without informing that other person of the revocation or non-extension, shall be guilty of an offence and the thermometer shall be liable to be forfeited.

(2) For the purposes of this regulation, an EEC sign or mark shall be regarded as related to a pattern approval if it is a sign framed by reference to that pattern approval or a mark of EEC initial verification which was affixed by reference to conformity to the pattern which was the subject of that pattern approval.

(3) A certificate by the Secretary of State stating that an EEC pattern approval granted by a member State other than the United Kingdom has been revoked and thereby ceased to have effect on a date specified shall be conclusive as to the matters certified in any proceedings for an offence under this regulation

(4) For the purposes of paragraph (1) and of regulation 12(2) a clinical thermometer shall not be regarded as bearing an EEC sign or mark if any such sign or mark on the thermometer has been obliterated in accordance with regulation 13.

Temporary prohibition of sale or use

12. –

(1) Where the Secretary of State is satisfied that clinical thermometers, constructed according to a pattern in respect of which an EEC pattern approval granted by any member State is in force, reveal in service a defect of a general nature which makes them unsuitable for their intended use, he may issue a prohibition notice under this regulation with respect to clinical thermometers of that pattern.

(2) For so long as a prohibition notice issued under this regulation is in force with respect to clinical thermometers of any pattern, any person who, knowing that such a notice has been issued with respect to such clinical thermometers, uses, or has in his possession for use, or knowingly causes or permits any other person to use, a clinical thermometers of the pattern in question bearing any EEC sign or mark related to that pattern approval, or disposes of any such clinical thermometers to any other person in a state in which it could be used without informing that other person of the prohibition notice, shall be guilty of an offence.

(3) A prohibition notice under this regulation shall give particulars of the pattern to which it relates.

(4) The Secretary of State may withdraw a prohibition notice at any time.

(5) If the Secretary of State issues a prohibition notice under this regulation he shall give a statement in writing of his grounds for doing so to any person appearing to him to be concerned.

(6) The Secretary of State shall cause to be published—

- (a) any prohibition notice issued under this regulation; and
- (b) any notice of withdrawal of any such prohibition notice.

Obliteration of EEC signs and marks

13.—(1) An inspector may obliterate any EEC sign or mark if he is satisfied that the clinical thermometer bearing the sign or mark—

- (a) falls outside the maximum permissible errors as provided by paragraph 8 of Annex I to the Directive; or
- (b) does not comply in some other respect with the requirements of the Directive.

(2) Without prejudice to paragraph (1), an inspector may, at the request of any person appearing to him to be the owner of a clinical thermometer, obliterate any EEC sign or mark on it which is related to an EEC pattern approval (whether granted under these Regulations or by any member State other than the United Kingdom) which the inspector is satisfied has ceased to have effect.

Unauthorised application of EEC signs and marks

14.—(1) Any person who, with intent to deceive—

- (a) not being a manufacturer authorised or required to do so under any provision of these Regulations or the duly authorised agent of any such manufacturer, marks a clinical thermometer with any EEC sign; or
- (b) forges, counterfeits or, except in accordance with regulation 13, in any way alters or defaces any EEC sign or mark on a clinical thermometer; or
- (c) makes any alteration to a clinical thermometer after any EEC sign or mark has been applied to it in accordance with these Regulations, so that it no longer complies with the requirements of the Directive,

shall be guilty of an offence

(2) Any person who uses for trade, sells or exposes or offers for sale any clinical thermometer which to his knowledge—

- (a) bears any EEC sign or mark which is a forgery or counterfeit, or which has been transferred from another clinical thermometer or other instrument, or which has been altered or defaced otherwise than under regulation 13; or
- (b) does not comply with the requirements of the Directive by reason of any alteration made to it after any EEC sign or mark was applied to it in accordance with these Regulations,

shall be guilty of an offence

(3) Any clinical thermometer in respect of which an offence under this regulation was committed, and any implement used in the commission of that offence in the possession of the person by whom the offence was committed shall be liable to be forfeited.

Powers of inspection

15.—(1) Subject to the production if so requested of his authority, an inspector may at all reasonable times—

- (a) inspect and test any clinical thermometer; and
- (b) enter any premises at which he has reasonable cause to believe there to be a clinical thermometer, not being premises used only as a private dwelling house.

(2) Subject to the production if so requested of his authority, an inspector may at any time seize and detain any clinical thermometer which he has reasonable cause to believe is liable to be forfeited under these Regulations.

Obstruction of inspectors

16.—(1) Any person who—

- (a) intentionally obstructs an inspector acting in the execution of any provision of these Regulations; or

(b) without reasonable cause fails to give any inspector so acting any assistance or information which the inspector may reasonably require of him for the purposes of the performance by the inspector of his functions under these Regulations,
shall be guilty of an offence.

(2) If any person, in giving an inspector any such information as is mentioned in paragraph (1), gives any information which he knows to be false in a material particular, he shall be guilty of an offence.

Offences by corporations

17.—(1) Where an offence under any provision of these Regulations which has been committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of that body corporate, or any person who was purporting to act in any such capacity, he as well as the body corporate shall be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

(2) Where the affairs of a body corporate are managed by its members, paragraph (1) shall apply in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(3) Where an offence under these Regulations is committed in Scotland by a Scottish partnership and is proved to have been committed with the consent or connivance of, or to be attributed to any neglect on the part of, a partner, he as well as the partnership shall be guilty of the offence and be liable to be proceeded against and punished accordingly.

Institution of proceedings

18. Proceedings for any offence under these Regulations shall not be instituted—

- (a) in England and Wales, except by or on behalf of the Secretary of State or the chief officer of police for a police area; or
- (b) in Northern Ireland, except by the Department of Economic Development or the Director of Public Prosecutions for Northern Ireland.

Penalties for offences

19.—(1) Any person guilty of an offence under regulation 10, 11 or 12 shall be liable on summary conviction—

- (a) in Great Britain to a fine not exceeding level 5 on the standard scale, and
- (b) in Northern Ireland to a fine not exceeding £2000.

(2) Any person guilty of an offence under regulation 14 shall be liable on summary conviction—

- (a) in Great Britain to a fine not exceeding level 5 on the standard scale, and
- (b) in Northern Ireland to a fine not exceeding £2000; and

on indictment to a fine or to a term of imprisonment no exceeding 2 years or both.

(3) Any person guilty of an offence under regulation 16 shall be liable on summary conviction—

- (a) in Great Britain to a fine not exceeding level 3 on the standard scale, and
- (b) in Northern Ireland to a fine not exceeding £400.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

29th September 1993

Virginia Bottomley
Secretary of State for Health

SCHEDULE

Regulation 4(1)

EEC PATTERN APPROVAL AND INITIAL VERIFICATION THE EEC SIGNS AND MARKS

The EEC signs

1.—(1) The alternative sign of EEC pattern approval consists of the following, in the order set out—

- (a) a stylized letter ε ;
- (b) the letter or letters denoting the member State which granted the pattern approval using the same lettering system as in paragraph 1 of Schedule 1 to the 1988 Regulations;
- (c) the year in which the approval was granted; and
- (d) an identification mark determined by the metrological service of the member State which granted approval, clearly separated from the year.

(2) The following is an example of the alternative sign of EEC pattern approval in the form appropriate for an EEC pattern approval granted in the United Kingdom:

ε UK 93

(3) The identification mark referred to in sub-paragraph (1)(d) shall, in the United Kingdom sign of pattern approval, be a mark determined by the Secretary of State.

2.—(1) The alternative sign of EEC limited pattern approval is the same as the sign described in paragraph 1(1) above with the addition of a letter P before the stylized letter E in paragraph 1(1) (a) above, being a letter P of the same dimensions.

(2) The following is an example of the alternative sign of EEC limited pattern approval, in the form appropriate for an EEC limited pattern approval in the United Kingdom:

p ε UK 93

The EEC marks

3.—(1) The alternative mark of EEC initial verification consists of the following—

- (a) a small letter “e”;
- (b) the letter or letters denoting the member State in which initial verification took place, using the same lettering system as in paragraph 5 of Schedule 1 to the 1988 Regulations;
- (c) the year of initial verification; and
- (d) where necessary, the distinguishing number of the verifying agent or office, separated clearly from the year.

(2) In the case of a United Kingdom mark of EEC initial verification, the distinguishing number referred to in sub-paragraph (1)(d) shall be the distinguishing number of the person carrying out the examination.

(3) The following is an example of the alternative mark of initial verification, in the form appropriate for an EEC initial verification carried out in the United Kingdom:

e UK 93

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply to the United Kingdom, implement Council Directive No. [76/764/EEC](#), as amended, relating to clinical mercury-in-glass, maximum reading thermometers. They apply to clinical thermometers designed to measure the internal temperature of humans or animals (regulation 3).

The Regulations—

- (a) specify the signs of EEC pattern approval and EEC limited pattern approval and the mark of EEC initial verification (regulation 4 and the Schedule);
- (b) provide for the free movement in the United Kingdom of clinical thermometers which bear the sign of EEC pattern approval and the mark of EEC initial verification (regulation 5);
- (c) provide for the approval by the Secretary of State of bodies to grant EEC pattern approval and to carry out EEC initial verification in respect of clinical thermometers (regulation 6(1) to (5));
- (d) enable approval bodies to charge fees for things done in performance of their functions under the Regulations (regulation 6(6) to (9));
- (e) provide for the grant by approved bodies of EEC pattern approval of clinical thermometers which comply with the Directive (regulation 7);
- (f) provide for a sign of EEC pattern approval or EEC limited pattern approval to be affixed to clinical thermometers which conform to the approved pattern (regulation 8);
- (g) provide for approved bodies to carry out EEC initial verification of clinical thermometers to determine whether a pattern approval is in force and whether they conform to it and to the requirements of the Directive (regulation 9(1) and (2));
- (h) provide for a mark of EEC initial verification to be affixed to clinical thermometers which conform to the approved pattern and to the requirements of the Directive (regulation 9(3) and (4));
- (i) restrict the making of applications for initial verification where an EEC limited pattern approval is subject to a condition limiting the number of clinical thermometers which may be submitted for initial verification (regulation 10);
- (j) prohibit the use for trade of clinical thermometers in respect of which EEC pattern approval has been revoked or has not been extended (regulation 11);
- (k) provide for the temporary prohibition of the sale or use of clinical thermometers in respect of which an EEC pattern approval is in force but which reveal in service a defect which makes them unsuitable for their intended use (regulation 12);
- (l) enable an inspector to obliterate EEC signs and marks in specified circumstances (regulation 13);
- (m) prohibit the unauthorised application of EEC signs and marks (regulation 14);
- (n) provide for powers of inspectors, obstruction of inspectors, offences by corporations and the institution of proceedings and specified penalties (regulations 15 to 19).