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STATUTORY INSTRUMENTS

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**1994 No. 3017**

**CONSUMER PROTECTION**

**The Medical Devices Regulations 1994**

<i>Made</i>	- - - -	<i>28th November 1994</i>
<i>Laid before Parliament</i>		<i>30th November 1994</i>
<i>Coming into force</i>		
<i>for the purposes of regulation 17</i>		<i>21st December 1994</i>
<i>for all other purposes</i>		<i>1st January 1995</i>

The Secretary of State, in exercise of the powers conferred by sections 11 and 27(2) of the Consumer Protection Act 1987<sup>(1)</sup>, after consultation in accordance with section 11(5) of that Act with organisations appearing to her to be representative of interests substantially affected by these Regulations, with such other persons as appear to her to be appropriate and with the Health and Safety Commission, and the Secretary of State as respects Great Britain and the Department of Health and Social Services for Northern Ireland as respects Northern Ireland, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972<sup>(2)</sup> and in each case in exercise of all other powers so enabling them, hereby make the following Regulations:—

**Citation and commencement**

1. These Regulations may be cited as the Medical Devices Regulations 1994 and shall come into force—

- (a) for the purposes of regulation 17 on 21st December 1994; and
- (b) for all other purposes on 1st January 1995.

**Interpretation**

2.—(1) In these Regulations, unless the context requires otherwise—

“the 1987 Act” means the Consumer Protection Act 1987;

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(1) 1987 c. 43.

(2) See S.I.1993/2661, Article 2, which designates the Secretary of State and the Department of Health and Social Services for Northern Ireland for the purposes of section 2(2) in relation to medical devices.

“accessory” means an article which, whilst not being a device, is intended specifically by its manufacturer to be used together with a device to enable the device to be used as intended by its manufacturer;

“Annex” means an Annex to the Directive, and a reference in these Regulations to a numbered Annex is to the Annex of the Directive which is so numbered;

“authorised representative” means an authorised representative established within the Community;

“CE marking” means the marking which indicates that one or more of the procedures referred to in regulations 7, 8, 9, 10 and 11 has, or, as the case may be, have been followed and which consists of a symbol comprising the letters “CE” the form and dimensions of which are as specified in Annex XII;

“the Community” means the European Economic Area established under the EEA Agreement but until that Agreement comes into force in relation to Liechtenstein does not include the State of Liechtenstein;

“custom-made” means, in relation to a device—

- (a) that it is manufactured specifically in accordance with a written prescription of a duly qualified medical practitioner or a professional user which gives, under his responsibility, specific characteristics as to its design; and
- (b) that it is intended for the sole use of a particular patient,

but does not include a mass-produced product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user;

“device” means a medical device, that is to say an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which—

- (a) is intended by the manufacturer to be used for human beings for the purpose of—
  - (i) diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
  - (iii) investigation, replacement or modification of the anatomy or of a physiological process, or
  - (iv) control of conception; and
- (b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,

even if it is intended to administer a medicinal product as defined in Council Directive [65/65/EEC](#)(3) or incorporates as an integral part a substance which, if used separately, would be a medicinal product as so defined and which is liable to act upon the body with action ancillary to that of the device;

“the Directive” means Council Directive [93/42/EEC](#) concerning medical devices(4);

“the EEA Agreement” means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992 as adjusted by the Protocol signed at Brussels on 17th March 1993(5);

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(3) OJ No. 22, 9.6.65, p. 369/65.

(4) OJ No. L. 169, 12.7.93, p. 1.

(5) Protocol 47 and certain Annexes to the EEA Agreement were amended by Decision No. 7/94 of the EEA Joint Committee of 21st March 1994 which came into force on 1st July 1994 (OJ No. L 160, 28.6.94, p. 1). Chapter XXX of Annex II to the EEA Agreement was added by item U in Annex 3 to the said Decision. Council Directive [93/42/EEC](#) was added at point 1 of the said Chapter XXX.

“EEA State” means a State which is a Contracting Party to the EEA Agreement but until the EEA Agreement comes into force in relation to Liechtenstein does not include the State of Liechtenstein;

“essential requirements” means the requirements specified in Annex I and “relevant essential requirements” in relation to a device means such of those requirements, or such aspects of those requirements, as apply to it, not including, in the case of a device intended for clinical investigation, such of those requirements, or aspects of them, as are the subject of the investigation;

“harmonised Standard” means—

- (a) a technical specification adopted by the European Committee for Standardisation or the European Committee for Electrotechnical Standardisation, or both of them, upon a remit from the European Commission pursuant to Council Directive [83/189/EEC\(6\)](#) laying down a procedure for the provision of information in the field of technical standards and regulations, as amended by Council Directive [88/182/EEC\(7\)](#), Council Directive [90/320/EEC\(8\)](#) and European Parliament and Council Directive [94/10/EC\(9\)](#), and the reference of which has been published in the Official Journal of the European Communities; or
- (b) a monograph of the European Pharmacopoeia and in particular any monograph on surgical sutures or on interaction between medicinal products and materials used in devices containing medicinal products, the reference of which has been published in the Official Journal of the European Communities;

“intended for clinical investigation” means, in relation to a device, that it is intended for use by a duly qualified medical practitioner or a professional user when conducting investigations of that device in an adequate human clinical environment;

“intended purpose” means, in relation to a device, the use for which it is intended according to the data supplied by the manufacturer on the labelling, and—

- (a) the instructions;
- (b) the promotional materials; or
- (c) the instructions and the promotional materials;

“manufacturer” means the person who is responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party;

“medical practitioner” means a registered medical practitioner;

“notified body” means, in relation to any task, a body designated and notified in respect of that task in accordance with Article 16 of the Directive;

“placing on the market” means, in relation to a device, the first making available in return for payment or free of charge of a new or fully refurbished device other than a device intended for clinical investigation, with a view to distribution, use, or both, on the Community market;

“putting into service” means, in relation to a device, making it ready for use on the Community market for the first time for its intended purpose;

“relevant national Standard” means, in relation to an essential requirement or an aspect of it, a Standard—

- (a) which contains a technical specification or a description relating to that requirement or aspect;

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(6) OJ No. L 109, 26.4.83, p. 8.  
(7) OJ No. L 81, 26.3.88, p. 75.  
(8) OJ No. L 128, 18.5.90, p. 15.  
(9) OJ No. L 100, 19.4.94, p. 30.

- (b) which corresponds to a harmonised Standard containing such a specification or description; and
- (c) of which the reference number is published in the United Kingdom by the Secretary of State by notice in the London, Edinburgh and Belfast Gazettes or in another member State;

“relevant notified body identification number” means the identification number of the notified body which was responsible for carrying out tasks of the notified body under Annex II, IV, V or VI as respects a procedure which has been followed by the manufacturer of a device;

“used for *in vitro* diagnosis” means, in relation to a device, that it is a reagent, reagent product, kit, instrument, equipment or system, whether used alone or in combination and that it is intended by the manufacturer to be used *in vitro* for the examination of samples derived from the human body with a view to providing information on the physiological state, state of health or disease, or congenital abnormality thereof,

and any other words and expressions used both in these Regulations and in the Directive shall bear the same meaning in these Regulations as they have in the Directive.

(2) In these Regulations, unless the context requires otherwise, a reference to a numbered regulation is to the regulation of these Regulations which is so numbered, a reference in a regulation to a numbered paragraph is to the paragraph of that regulation which is so numbered, and a reference in a paragraph to a numbered or lettered sub-paragraph is to the sub-paragraph of that paragraph which is so numbered or lettered.

### Application of Regulations

3.—(1) Subject to paragraph (2), these Regulations shall apply to medical devices and their accessories and, for the purposes of these Regulations, accessories shall be treated as devices in their own right.

(2) These Regulations shall not apply to—

- (a) devices used for *in vitro* diagnosis;
- (b) active implantable devices covered by Council Directive [90/385/EEC\(10\)](#) as amended by the Directive and by Council Directive [93/68/EEC\(11\)](#);
- (c) medicinal products covered by Council Directive [65/65/EEC](#) as last amended by Council Directive [93/39/EEC\(12\)](#);
- (d) cosmetic products covered by Council Directive [76/768/EEC\(13\)](#) as last amended by Council Directive [93/47/EEC\(14\)](#);
- (e) human blood, human blood products, human plasma or blood cells of human origin or devices which incorporate at the time of placing on the market such blood products, plasma or cells;
  - (f) transplants or tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin;
  - (g) transplants or tissues or cells of animal origin, unless a device is manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue; or

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(10) OJ No. L 189, 20.7.90, p. 17.

(11) OJ No. L 220, 30.8.93, p. 1.

(12) OJ No. L 214, 24.8.93, p. 22.

(13) OJ No. L 262, 27.9.76, p. 169.

(14) OJ No. L 203, 13.8.93, p. 24.

(h) products whose principal intended purpose is such that they fall under Council Directive [89/686/EEC\(15\)](#) as amended by Council Directive [93/68/EEC](#).

(3) Except for the purposes of regulation 5(2), these Regulations shall not apply to devices intended to administer a medicinal product within the meaning of Article 1 of Council Directive [65/65/EEC](#) where the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable.

(4) References in subsequent provisions of these Regulations to devices are references to devices to which these Regulations apply in accordance with the preceding paragraphs of this regulation.

### **Classification of devices**

4.—(1) For the purposes of these Regulations, devices are classified into Classes I, IIa, IIb and III in accordance with the definitions, implementing rules and classification rules set out in Annex IX.

(2) In the event of a dispute between the manufacturer and a notified body resulting from the application of the definitions and rules referred to in paragraph (1), the matter shall be referred to the Secretary of State for decision.

### **Essential requirements for devices**

5.—(1) Subject to paragraph (2), all devices placed on the market or put into service must comply with the relevant essential requirements.

(2) The devices mentioned in regulation 3(3) which are placed on the market or put into service must comply with such of the relevant essential requirements as relate to safety or performance.

(3) In determining which are the relevant essential requirements for a device and whether or not the device complies with any of the relevant essential requirements account shall be taken of its intended purpose.

(4) Where confirmation of conformity with the essential requirements must be based on clinical data, such data must be established in accordance with the requirements set out in Annex X.

(5) In the case of a device which has been put into service—

(a) the essential requirements specified in Sections 8.7 and 13 of Annex I with regard to information on the packaging and on any label are complied with only if such information is in English (whether or not it is also in another language and whether or not the device is for professional use); and

(b) the essential requirements specified in Sections 11.4 and 13 of Annex I with regard to instructions for use are complied with only if such instructions are in English or another Community language.

(6) Where the instructions for use referred to in paragraph (5)(b) are not in English, any packaging, label or promotional literature must carry a clear statement in English stating the language in which the instructions are given.

(7) A device shall be treated as complying with an essential requirement if it conforms as respects that requirement to a relevant national Standard unless there are reasonable grounds for suspecting that the device does not comply with that requirement.

(8) A device which is neither custom-made nor intended for clinical investigation and which bears the CE marking shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

(9) A custom-made device in respect of which the conditions specified in Annex VIII are satisfied, and in the case of a Class IIa, Class IIb and Class III device, which is accompanied by the

statement required by Section 1 of Annex VIII, shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

- (10) A device intended for clinical investigation in respect of which—
- (a) notice has been given under regulation 16(1);
  - (b) the conditions specified in Annex VIII are satisfied; and
  - (c) either—
    - (i) no notice has been given under regulation 16(2) within the period of 60 days there referred to, or
    - (ii) notice has been given under regulation 16(3),
 shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

### **CE marking**

6.—(1) Except as provided by paragraph (2), every device placed on the market shall bear the CE marking (affixed following a procedure mentioned in regulation 7, 8, 9, 10 or 11, whether carried out in the United Kingdom or elsewhere) in a visible, legible and indelible form—

- (a) on the device or its sterile pack, where practicable and appropriate;
- (b) on the instructions for use; and
- (c) where applicable, on the sales packaging,

and, where relevant, the marking shall be accompanied by the relevant notified body identification number.

(2) Paragraph (1) shall not apply to a device which is custom-made or intended for clinical investigation.

(3) No device shall bear a mark or inscription which is likely to mislead third parties with regard to the meaning or the graphics of the CE marking.

(4) Any other mark may be affixed to a device, its packaging or accompanying instruction leaflet, provided that the visibility and legibility of the CE marking are not thereby reduced.

(5) Where a device comes within the scope of a directive other than the Directive and that other directive provides for the affixing of the CE marking, the CE marking shall not be affixed unless the relevant requirements of that other directive are also satisfied.

(6) Where a directive other than the Directive permits a manufacturer to choose which arrangements to apply during a transitional period, the CE marking shall indicate that the device fulfils only the provisions of those directives applied by the manufacturer.

(7) In a case falling within paragraph (6), particulars of the directives applied by the manufacturer, as published in the Official Journal of the European Communities, shall be given in the documents, notices or instructions required by the directives and accompanying the device.

### **Procedure for affixing CE marking for Class I devices**

7. A device falling within Class I may bear the CE marking only if its manufacturer follows the EC declaration of conformity procedure specified in Annex VII.

### **Procedure for affixing CE marking for Class IIa devices**

8. A device falling within Class IIa may bear the CE marking only if its manufacturer—

- (a) follows the EC declaration of conformity procedure (full quality assurance system) set out in Annex II, excluding Section 4 of that Annex; or
- (b) follows the EC declaration of conformity procedure set out in Annex VII, together with—
  - (i) the EC verification procedure set out in Annex IV,
  - (ii) the EC declaration of conformity procedure (production quality assurance) set out in Annex V, or
  - (iii) the EC declaration of conformity procedure (product quality assurance) set out in Annex VI.

#### **Procedure for affixing CE marking for Class IIb devices**

9. A device falling within Class IIb may bear the CE marking only if its manufacturer—
- (a) follows the EC declaration of conformity procedure (full quality assurance system) set out in Annex II, excluding Section 4 of that Annex; or
  - (b) follows the EC type-examination procedure set out in Annex III, together with—
    - (i) the EC verification procedure set out in Annex IV,
    - (ii) the EC declaration of conformity procedure (production quality assurance) set out in Annex V, or
    - (iii) the EC declaration of conformity procedure (product quality assurance) set out in Annex VI.

#### **Procedure for affixing CE marking for Class III devices**

10. A device falling within Class III may bear the CE marking only if its manufacturer—
- (a) follows the EC declaration of conformity procedure (full quality assurance system) set out in Annex II; or
  - (b) follows the EC type-examination procedure set out in Annex III, together with—
    - (i) the EC verification procedure set out in Annex IV, or
    - (ii) the EC declaration of conformity procedure (production quality assurance) set out in Annex V.

#### **Procedure for systems and procedure packs, and devices to be sterilised before use**

11.—(1) Any person who puts together devices bearing the CE marking within their intended purpose and within the limits of use specified by their manufacturers in order to place them on the market as a system or procedure pack shall draw up a declaration that—

- (a) he has verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and he has carried out his operations in accordance with these instructions;
- (b) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
- (c) his operations are subjected to appropriate methods of internal control and inspection.

(2) A system or procedure pack shall be treated as a device in its own right and shall be subjected to the relevant procedure under regulation 7, 8, 9 or 10 where—

- (a) it incorporates any device which does not bear a CE marking; or
- (b) the chosen combination of devices is intended to be put to a different use from any intended by the manufacturer of each device.

(3) Any person who, for the purposes of placing on the market a system or procedure pack referred to in paragraph (2) or a CE marked medical device designed by its manufacturer to be sterilised before use, shall—

- (a) for the purposes of validating a sterilisation procedure, follow one of the procedures referred to in Annex IV, Annex V or Annex VI as it relates to the obtaining of sterility; and
- (b) make a written declaration that sterilisation has been carried out in accordance with the manufacturer's instructions.

(4) A conformity assessment procedure carried out by a notified body in relation to a system or procedure pack or device referred to in paragraph (3) shall be limited to the procedures referred to in paragraph (3)(a).

(5) A system or procedure pack solely made up of devices bearing the CE marking—

- (a) shall not bear an additional CE marking; and
- (b) shall be accompanied by the information referred to in Section 13 of Annex I which shall include, where appropriate, the information supplied by the manufacturers of the devices which have been put together.

(6) The declaration referred to in paragraphs (1) and (3)(b) shall be kept available for the Secretary of State for a period of five years.

### **General provisions relating to conformity assessment procedures**

**12.**—(1) A notified body which is responsible for carrying out a conformity assessment procedure in connection with a device under regulation 7, 8, 9, 10 or 11 shall, in doing so, take account of any relevant information relating to the characteristics and performance of that device, including in particular the results of any relevant tests and verification relating to that device already carried out under the laws or administrative provisions in force before 1st January 1995 in any EEA State.

(2) Any manufacturer of a device or any notified body shall, in carrying out a conformity assessment procedure for affixing the CE marking to a device, take account of the results of any assessment or verification operations which have been carried out in accordance with the Directive or these Regulations at an intermediate stage of manufacture of the device.

(3) Any procedure set out in Annex III, IV, VII or VIII which, by virtue of these Regulations, is to be followed in the United Kingdom by a manufacturer who has no place of business there may be initiated there by his authorised representative.

(4) Where a conformity assessment procedure involves the intervention of a notified body, the manufacturer of a device or his authorised representative may apply to any notified body which has been designated in accordance with Article 16 of the Directive to carry out tasks in respect of that type of device for the purposes of that conformity assessment procedure.

(5) Where a manufacturer has supplied information or data to a notified body in the course of a conformity assessment procedure, the notified body may require the manufacturer to provide any additional information or data which the notified body considers necessary for the purposes of that procedure.

(6) A decision made by a notified body in accordance with Annex II or Annex III shall—

- (a) specify the period of validity of the decision; and
- (b) be valid for an initial period of not more than 5 years.

(7) Where an agreement under which a notified body agrees to carry out a conformity assessment procedure for a manufacturer allows the manufacturer to apply to the notified body at a specified time for an extension of the period of validity of a decision mentioned in paragraph (6), the notified body may extend the validity of the decision for further periods of 5 years, each such period commencing on the expiry of the preceding period.



(8) The documentation relating to any of the procedures referred to in this regulation carried out in the United Kingdom shall be in English or, subject to regulation 5(5) and (6), in some other language acceptable to the notified body concerned.

(9) Where the procedures referred to in regulation 7, 8, 9, 10 or 15 have not been carried out in relation to an individual device, the Secretary of State may authorise the placing on the market and putting into service of that device if she is satisfied that this would be in the interest of protection of health.

(10) A manufacturer shall, in following a conformity assessment procedure, observe the manufacturer's obligations set out in the Annex on that procedure.

(11) In so far as a conformity assessment procedure relates to tasks to be carried out by a notified body, that body shall carry out the notified body's tasks set out in the Annex on that procedure and shall do so in accordance with that Annex.

### **Obligations of persons other than manufacturers**

**13.**—(1) Subject to paragraph (2), any obligation of a manufacturer under these Regulations shall extend to a person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name.

(2) Paragraph (1) shall not apply to a person who assembles or adapts devices already on the market to their intended purpose for an individual patient.

(3) Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep available the technical documentation referred to in Section 6.3 of Annex II or Section 7.4 of Annex III shall fall upon the person responsible for placing on the market the device to which the documentation relates or upon the importer referred to in Section 13.3(a) of Annex I.

(4) Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep available the technical documentation referred to in Section 2 of Annex VII shall fall upon the person who places on the market the device to which the documentation relates.

### **Registration of persons placing devices on the market**

**14.**—(1) A manufacturer with a registered place of business in the United Kingdom who, under his own name, places a device on the market in accordance with the procedures referred to in regulation 7 or regulation 15(1) shall—

- (a) inform the Secretary of State of the address of that registered place of business; and
- (b) supply the Secretary of State with a description of each category of device concerned.

(2) Any person with a registered place of business in the United Kingdom who is engaged in the activities referred to in regulation 11 shall—

- (a) inform the Secretary of State of the address of that registered place of business; and
- (b) supply the Secretary of State with descriptions of the devices to which that regulation applies which are sufficient to identify them.

(3) Any person with a registered place of business in the United Kingdom who places on the market a device referred to in paragraph (1) on behalf of a manufacturer who does not have a registered place of business in the Community shall inform the Secretary of State of—

- (a) the address of his registered place of business; and
- (b) the category of device.

### **Custom-made devices**

- 15.**—(1) Before a custom-made device is placed on the market its manufacturer shall—
- (a) draw up a statement containing the information required by Sections 1, 2 and 2.1 of Annex VIII;
  - (b) undertake to keep available for the Secretary of State documentation allowing an understanding of the design, manufacture and performances of the device, including the expected performances, so as to allow assessment of conformity of the device with the requirements of these Regulations; and
  - (c) take all necessary measures to ensure that the manufacturing process ensures that each device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.1 of Annex VIII.
- (2) The information contained in the statement referred to in paragraph (1)(a) and in the undertaking referred to in paragraph (1)(b) shall be kept available for a minimum period of 5 years.

### **Clinical investigations**

- 16.**—(1) Before devices intended for clinical investigation are made available to a medical practitioner or authorised qualified person for the purposes of a clinical investigation to take place within the United Kingdom, their manufacturer or his authorised representative shall give at least 60 days' prior notice in writing to the Secretary of State of the making available of the devices for the intended investigation, in the form of—
- (a) the statement required by Sections 1, 2 and 2.2 of Annex VIII; and
  - (b) the undertaking to keep available for the Secretary of State the documentation referred to in Section 3.2 of Annex VIII.
- (2) If, within 60 days of the giving of that notice, the Secretary of State gives written notice to the manufacturer or authorised representative, whichever gave the notice to her under paragraph (1), that, on grounds of public health or public policy, devices should not be made available for the purposes of that investigation, devices may not be made available for those purposes pursuant to that notice under paragraph (1).
- (3) Where the relevant ethics committee has issued a favourable opinion on a programme of clinical investigation, the Secretary of State may give written notice to the manufacturer or his authorised representative within 60 days of the giving of notice under paragraph (1) that devices may be made available for the purposes of that investigation at any time after the giving of notice under that paragraph.
- (4) The manufacturer of a device intended for clinical investigation shall—
- (a) take all necessary measures to ensure that the manufacturing process ensures that a device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.2 of Annex VIII; and
  - (b) authorise the assessment, including audit where necessary, of the effectiveness of the measures which he takes pursuant to this regulation.
- (5) The manufacturer or his authorised representative shall—
- (a) keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex X; and
  - (b) keep the information contained in the statement and the undertaking referred to in paragraph (1) for a minimum period of 5 years.
- (6) Clinical investigations shall be conducted in accordance with the provisions of Annex X.

(7) Paragraphs (1), (2) and (3) do not apply where clinical investigations are conducted using devices which are authorised in accordance with regulation 7, 8, 9 or 10 to bear the CE marking unless the aim of those investigations is to determine whether the device in question may be used for a purpose other than that referred to in the relevant conformity assessment procedure.

(8) The grounds on which a notice may be given under paragraph (2) include the grounds that the Secretary of State is not satisfied as to the safety of a device for the intended purposes because—

- (a) the manufacturer does not authorise an assessment by the Secretary of State, whether by means of an audit, and inspection or otherwise, of the effectiveness of the measures referred to in paragraph (4); or
- (b) the manufacturer or his authorised representative does not make available to the Secretary of State documentation which he has undertaken to keep available in accordance with paragraph (1)(b).

### **Notified bodies**

**17.**—(1) The Secretary of State may designate for the purposes of Article 16 of the Directive any corporate or other body as a body which is to carry out tasks as part of a procedure mentioned in regulation 7, 8, 9, or 10 and, if she so designates a body, she shall designate the tasks which it is to carry out.

(2) A body shall be designated under paragraph (1) only if—

- (a) it has applied to be, or agrees to be, so designated; and
- (b) it is a body in respect of which the conditions specified in Annex XI are fulfilled as respects the tasks which it is to carry out.

(3) The Secretary of State shall withdraw any designation of a body under paragraph (1) if the body so requests or if she considers that it is no longer a body in respect of which the conditions specified in Annex XI are fulfilled as respects the tasks which it is to carry out.

(4) The Secretary of State may vary the designation of tasks which a notified body is to carry out by—

- (a) limiting or removing the tasks; or
- (b) on the application of the notified body, extending or adding to the tasks.

(5) The Secretary of State may refuse to designate a body as a notified body, or may withdraw designation of a body as a notified body if it fails to pay any fee or other charge in accordance with regulations made under section 56 of the Finance Act 1973<sup>(16)</sup> in connection with services provided by the Secretary of State in carrying out her functions as competent authority for the purposes of the Directive.

(6) Before withdrawing designation under paragraph (3), otherwise than at the notified body's request, and before effecting a variation under paragraph (4)(a), the Secretary of State shall give to the notified body an opportunity to make representations to her in writing and shall take into account any such representations as are made.

(7) For the purpose of deciding whether or not a body is one in respect of which the conditions specified in Annex XI are fulfilled as respects the tasks which it carries out or is to carry out, the Secretary of State may arrange for the inspection of—

- (a) any premises occupied, or plant or equipment used, in connection with the carrying out of any such task; or
- (b) any premises occupied, or plant or equipment used, by a manufacturer where the body is a notified body undertaking any task in relation to that manufacturer,

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(16) 1973 c. 51.

and may take into account for the purposes of her decision any refusal of reasonable facilities for such inspection and the results of any such inspection.

### **Prohibition on supply etc.**

**18.**—(1) Subject to paragraph (6) the supply, offer to supply, agreement to supply, exposure for supply or possession for supply of a device, which constitutes placing on the market or putting into service a device which does not comply with the relevant essential requirements, is prohibited.

(2) Subject to paragraphs (3) and (6), the supply, offer to supply, agreement to supply, exposure for supply or possession for supply of a device—

- (a) which does not bear the CE marking as required by regulation 6(1); or
- (b) which bears a mark in contravention of regulation 6(3),

is prohibited.

(3) Paragraph (2)(a) does not apply to a device which is custom-made or intended for clinical investigation.

(4) The supply of a custom-made device in respect of which the manufacturer has contravened regulation 15 is prohibited.

(5) The supply, in contravention of regulation 16(1) or a notice under regulation 16(2), of a device intended for clinical investigation is prohibited.

(6) Nothing in paragraphs (1) or (2) prevents the offer to supply, the exposure for supply or the possession for supply at a trade fair, exhibition, demonstration or similar event of a device which does not comply with the relevant essential requirements or which does not bear the CE marking, provided that a notice is prominently displayed at the event, so as to be readily visible to a prospective purchaser, indicating that the device—

- (a) does not comply with those requirements or does not bear that marking; and
- (b) may not be put into service until it complies with the requirements of the Directive.

### **Enforcement etc.**

**19.**—(1) Notwithstanding that they are made partly in exercise of powers other than those conferred by section 11 of the 1987 Act, these Regulations shall be regarded for all purposes relating to enforcement (whether by criminal proceedings or notices or otherwise) and for the purposes of section 38 of that Act (disclosure of information) as safety regulations as defined in that Act and any provision of these Regulations made under those other powers shall be regarded for those purposes as a safety provision as defined in that Act.

(2) Except as provided by paragraph (3), each weights and measures authority in Great Britain and each district council in Northern Ireland is relieved of its duty imposed by section 27(1) of the 1987 Act in so far as it is exercisable in relation to devices, and that duty is transferred to the Secretary of State.

(3) Paragraph (2) shall not relieve an authority or council of its duty in relation to devices which are consumer goods for the purposes of Part II of the 1987 Act and accordingly each weights and measures authority in Great Britain and each district council in Northern Ireland shall, concurrently with the Secretary of State, enforce these Regulations in relation to such devices.

(4) Each authority and council referred to in paragraph (3) on whom a duty is imposed by section 27(1) of the 1987 Act to enforce the provisions of these Regulations shall give immediate notice to the Secretary of State of—

- (a) any suspension notice served by it under section 14 of that Act in respect of a device to which paragraph (3) applies;

- (b) any application made by it under section 16 of that Act for an order for forfeiture of any such device; and
- (c) any other thing done by it in respect of such a device for the purposes of, or in connection with the operation of, sections 14 to 17 of that Act.

(5) The powers conferred by section 13 of the 1987 Act to serve prohibition notices and notices to warn are exercisable in relation to non-conforming devices as they are exercisable in relation to relevant goods which the Secretary of State considers are unsafe (as well as being exercisable in relation to such goods), and in relation to non-conforming devices Schedule 2 to the 1987 Act shall have effect as if references to goods being unsafe or safe were references to devices being or not being non-conforming devices.

(6) In paragraph (5) “non-conforming devices” means devices which, whether or not the Secretary of State considers them unsafe, she considers to be devices to which the CE marking has been wrongly applied and to be devices—

- (a) which do not conform as respects a relevant essential requirement to a relevant national Standard where the device is held out as respects that essential requirement as conforming to that Standard;
- (b) where the devices are ones to which the CE marking has been applied following the EC declaration of conformity procedure, in respect of which the manufacturer or his authorised representative has failed to comply with his obligations under that procedure; or
- (c) where the devices are ones to which the CE marking has been applied following the EC type-examination procedure, which do not conform to the type described in the relevant EC type-examination certificate or which conform to such a type which does not meet the relevant essential requirements.

(7) Except in the case of a device which in the opinion of an enforcement authority is likely to compromise the health or safety of any person, where an enforcement authority has reasonable grounds for suspecting that the CE marking has been affixed to any device in relation to which any provision of these Regulations has not been complied with, that authority may serve upon the manufacturer or his authorised representative a notice—

- (a) specifying the description of the device to which the notice relates;
- (b) stating that the enforcement authority suspects that the CE marking has been affixed to the device in circumstances where a provision of these Regulations has not been complied with and the reasons for that suspicion;
- (c) specifying the provision referred to in sub-paragraph (b);
- (d) requiring the person on whom the notice is served—
  - (i) to secure that any device to which the notice relates conforms as regards the provision concerning the CE marking within such period as may be specified in the notice, or
  - (ii) to provide evidence within that period to the satisfaction of the enforcement authority that all the provisions of these Regulations have been complied with so far as they relate to that device; and
- (e) warning the person on whom the notice is served that unless the requirements of sub-paragraph (d) are met, further action may be taken under these Regulations in respect of that device or any device of the same type supplied by that person.

(8) Where an enforcement authority serves a notice referred to in paragraph (7), section 14, 16 or 17 of the 1987 Act shall not be applied as respects any device to which the notice relates until the period referred to in paragraph (7)(d) has expired and unless at the expiry of that period the person on whom the notice was served has failed to comply with its requirements.

(9) The notice referred to in paragraph (7) may include directions as to the measures to be taken by the person on whom the notice is served to secure conformity of the device with the provisions of these Regulations including different ways of securing conformity; and any such directions as are included are requirements of the notice for the purposes of paragraph (8).

#### **Centralised system of records etc.**

**20.** The Secretary of State shall perform, as respects the United Kingdom, the functions of the member State under Article 10 of the Directive.

#### **Fees**

**21.—(1)** A notified body may charge a fee in accordance with paragraphs (2), (3) and (4) for anything done in, or in connection with, performing a function required by or under any of the Annexes referred to in regulations 7, 8, 9, 10 and 11 to be performed by a notified body.

(2) Except as provided by paragraph (3), 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.

(3) Where the notified 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 notified body; and
- (b) the commercial rate normally charged in respect of profit for that work or similar work.

(4) The notified 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.

#### **Transitional provisions**

**22.—(1)** Nothing in regulation 18(1), (2) or (4)—

- (a) shall prohibit the supply before 14th June 1998 of a device, if the supply of the device is in accordance with the laws of that part of the United Kingdom in which it is supplied as in force on 31st December 1994; or
- (b) shall prohibit the supply before 1st July 2004 of a device which has been subjected to EEC pattern approval before 1st January 1995 in accordance with the Clinical Thermometers (EEC Requirements) Regulations 1993(17).

(2) In paragraph (1) “supply” means the supply, offer to supply, agreement to supply, exposure for supply or possession for supply.

#### **Notification of decisions etc.**

**23.—(1)** Where a decision is taken by the Secretary of State or a notified body under these Regulations which results in the refusal of, or restrictions on, the placing on the market by, or the putting into service by, or the carrying out of clinical investigations by a person of a device, the Secretary of State who, or the notified body which, took the decision shall forthwith give to that person notice of the decision which shall include—

- (a) a statement of the grounds on which it is based; and
- (b) a statement of any legal remedies available to that person and of any time limits which apply to their exercise.

(2) The provisions of paragraph (1) are in addition to any more specific obligation placed upon the Secretary of State or the notified body elsewhere in these Regulations.

(3) Except in cases of emergency, the Secretary of State or a notified body which is considering making a decision referred to in paragraph (1), shall give the manufacturer or his authorised representative an opportunity to make representations to her or it (as the case may be) before the decision is taken.

#### **Amendment of Schedule 1 to the Provision and Use of Work Equipment Regulations 1992**

**24.** In Schedule 1 to the Provision and Use of Work Equipment Regulations 1992(18) there shall be added the following paragraph—

“**36.** Council Directive [93/42/EEC](#) concerning medical devices (OJNo. L169, 12.7.1993 p.1).”.

#### **Substitution for Schedule 1 to the Personal Protective Equipment at Work Regulations 1992**

**25.** For Schedule 1 to the Personal Protective Equipment at Work Regulations 1992(19) there shall be substituted the following Schedule—

##### “SCHEDULE 1

Regulation 4(3)(e)

##### RELEVANT COMMUNITY DIRECTIVES

**1.** Council Directive [89/686/EEC](#) on the approximation of the laws of the member States relating to personal protective equipment (OJ No. L399, 30.12.89, p.18).

**2.** Council Directive [93/42/EEC](#) concerning medical devices (OJ No. L169, 12.7.93, p.1).”.

#### **Amendment of the Clinical Thermometers (EEC Requirements) Regulations 1993**

**26.**—(1) The Clinical Thermometers (EEC Requirements) Regulations 1993 shall be amended in accordance with the following provisions of this regulation.

(2) In regulation 5 after the word “approval” there shall be inserted the words “granted before 1st January 1995”.

(3) For paragraph (1) of regulation 6 there shall be substituted the following paragraph—

“(1) On application made by the body, the Secretary of State may approve one or more bodies of persons to carry out EEC initial verification and to affix the EEC mark of initial verification in respect of clinical thermometers.”.

(4) In regulation 7 for the words from “Regulations 8 to 11 of the 1988 Regulations” to “and Schedule 2 to, the 1988 Regulations” there shall be substituted the words “Regulation 11 of the 1988 Regulations (which contains provisions with respect to the revocation of EEC pattern approval) shall apply in relation to the revocation of pattern approval of clinical thermometers to which these Regulations apply as they apply in relation to the revocation of pattern approval of instruments to which those Regulations apply as if in regulation 11 of the 1988 Regulations”.

#### **Amendment of the Electro-medical Equipment (EEC Requirements) Regulations 1988**

**27.**—(1) The Electro-medical Equipment (EEC Requirements) Regulations 1988(20) shall be amended in accordance with the following provisions of this regulation.

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(18) S.I. [1992/2932](#).

(19) S.I. [1992/2966](#).

(20) S.I. [1988/1586](#).

- (2) In regulation 2 (interpretation)—
- (a) for the definition of “the Directive” there shall be substituted the following definition—
- ““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 veterinary medicine<sup>(21)</sup>”;
- (b) in the definition of “electro-medical equipment” the words “human or” shall be omitted.
- (3) For regulation 3 (marking) there shall be substituted the following regulation—
- “**3.** A person shall be guilty of an offence where he supplies electro-medical equipment—
- (a) which does not comply with the technical requirements contained in Annex I to the Directive; and
- (i) which is marked with the reversed epsilon, (or with a mark so closely resembling it as to be taken to be the reversed epsilon), or
- (ii) to which a declaration has been applied; or
- (b) which is also a medical device for the purposes of the Medical Devices Regulations 1994<sup>(22)</sup> and which does not satisfy the essential requirements for that device specified in those Regulations.”.

22nd November 1994

*Virginia Bottomley*  
One of Her Majesty’s Principal Secretaries of  
State

*F. A. Elliott*

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland  
this

L.S.

28th day of November 1994.

*F. A. Elliott*  
Permanent Secretary

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(21) OJ No. L 300, 19.11.84, p. 179, as amended by Council Directive [93/42/EEC](#) (OJ No. L 169, 12.7.93, p. 1).

(22) S.I. [1994/3017](#).



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## EXPLANATORY NOTE

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

These Regulations (“the Regulations”) implement Council Directive [93/42/EEC](#) (“the Directive”) concerning medical devices.

The Directive is based on the Council resolution of 7 May 1985 on a new approach to technical harmonisation and standards. It lays down essential safety requirements which medical devices (“devices”) must satisfy.

Regulation 3 specifies those products and substances which are not devices for the purposes of the Regulations.

Regulation 4 provides for the classification of devices into Classes I, IIa, IIb and III for the purposes of the Regulations.

Regulation 5 provides that devices placed on the market or put into service must comply with the relevant essential requirements as defined by reference to the essential requirements specified in Annex I of the Directive. Regulation 5 also sets out the factors to be taken into consideration in deciding whether a device meets the essential requirements.

Regulation 6 requires devices other than custom-made devices or devices intended for clinical investigation to bear the CE marking. Regulation 6 also prohibits the use of a mark which is likely to be confused with the CE marking.

Regulations 7, 8, 9 and 10 specify the procedures which manufacturers must follow for affixing the CE marking to devices.

Regulation 11 sets out the requirements to be satisfied for placing devices on the market as a system or procedure pack and for CE marked devices designed by manufacturers to be sterilised before use.

Regulation 12 contains general provisions relating to the procedures for affixing the CE marking to a device.

Regulation 13 specifies the obligations to be met by persons other than manufacturers.

Regulation 14 requires persons placing devices on the market to supply the Secretary of State with certain information about themselves and the devices.

Regulation 15 specifies, by reference to Annex VIII of the Directive, the rules in respect of custom-made devices.

Regulation 16 specifies, by reference to Annex VIII of the Directive, the rules relating to devices intended for clinical investigation.

Regulation 17 provides for the approval of the notified bodies which are to carry out tasks as part of a procedure mentioned in regulation 7, 8, 9 or 10. Regulation 17 also requires that such bodies must meet conditions specified in Annex XI of the Directive.

Regulation 18 creates offences.

Regulation 19 provides that the Regulations are to be regarded for the purposes of enforcement as safety regulations and safety provisions as defined in the Consumer Protection Act 1987, although they are made partly in exercise of other powers.

Regulation 20 provides for the setting up of a centralised system of records containing information on incidents occurring after devices have been placed on the market.

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

Regulation 21 makes provision for the fees chargeable by the notified bodies for work done under the Regulations.

Regulation 22 contains transitional provisions.

Regulation 23 provides for the notification of decisions by the Secretary of State and the notified bodies.

Regulations 24 and 25 contain amendments required in consequence of the Regulations.

Regulation 26 contains amendments required to take account of transitional provisions affecting clinical thermometers.

Regulation 27 contains amendments required to take account of changes affecting electro-medical equipment.

A cost compliance assessment is available, copies of which have been placed in the libraries of both Houses of Parliament.

Copies of the assessment are also available from the Medical Devices Agency, Room 620, 14 Russell Square, London WC1B 5EP.