STATUTORY INSTRUMENTS

2002 No. 618

CONSUMER PROTECTION

The Medical Devices Regulations 2002

Made - - - - -	*20th May 2002*
Laid before Parliament	*21st May 2002*
Coming into force - -	*13th June 2002*

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1. Association Agreements
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The Secretary of State, being a Minister designated for the purposes of section 2(2) of the European Communities Act 1972(**a**) in relation to measures relating to medical devices(**b**), in exercise of the powers conferred by the said section 2(2), in exercise, with the consent of the Treasury, of the powers conferred by section 56(1) and (2) of the Finance Act 1973(**c**), in exercise of the powers conferred by sections 11 and 27(2) of the Consumer Protection Act 1987(**d**), and in exercise of all other powers enabling him in that behalf, after consultation in accordance with section 11(5) of the Consumer Protection Act 1987 with organisations appearing to him to be representative of interests substantially affected by these Regulations, with such other persons considered by him appropriate and with the Health and Safety Commission, hereby makes the following Regulations:—

PART I

Introductory Provisions Relating to all Medical Devices

Citation and commencement

1. These Regulations may be cited as the Medical Devices Regulations 2002 and shall come into force 13th June 2002.

(**a**) 1972 c. 68.
(**b**) The Secretary of State was designated in relation to measures relating to active implantable medical devices in S.I. 1991/2289, and in relation to measures relating to medical devices other than active implantable medical devices in S.I. 1993/2661.
(**c**) 1973 c. 51.
(**d**) 1987 c. 43.

Interpretation

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

"the 1987 Act" means the Consumer Protection Act 1987;

"active implantable medical device" means a medical device which—

(a) relies for its functioning on a source of electrical energy or a source of power other than that generated directly by the human body or by gravity; and

(b) is intended to be totally or partially introduced into the human body (whether surgically or medically, including being introduced into a natural orifice) and which is intended to remain in the human body after completion of the surgical or medical procedure during which it is introduced,

even if it is intended to administer a medicinal product or incorporates as an integral part a substance which, if used separately, would be a medicinal product;

"Association Agreement" means an Agreement, listed in Schedule 1, establishing an Association between the European Communities and their Member States, on the one part, and another State on the other part (referred to in these Regulations as a "State which is a Party to an Association Agreement") on Conformity Assessment and Acceptance of Industrial Products;

"authorised representative" means a person established within the Community or in a State which is a Party to an Association Agreement who, explicitly designated by the manufacturer, acts for the manufacturer and may be addressed by authorities and bodies in the Community instead of the manufacturer;

"CE marking" means a conformity marking consisting of the initials "CE";

"the Community" means—

(a) in the context of any requirement relating to an *in vitro* diagnostic medical device, the European Community;

(b) in the context of any requirement relating to any other medical device, the European Economic Area;

"device for performance evaluation" means a product which is intended by its manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analysis or in other appropriate environments outside his own premises;

"Directive 90/385" means Council Directive 90/385/EEC of 20th June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices(**a**), as amended(**b**);

"Directive 93/42" means Council Directive 93/42/EEC of 14th June 1993 concerning medical devices(**c**), as amended(**d**);

"Directive 98/79" means Directive 98/79/EC of the European Parliament and of the Council of 27th October 1998 on *in vitro* diagnostic medical devices(**e**);

"Directive 2001/83" means Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community Code relating to medicinal products for human use(**f**);

"EC CAB" shall be construed in accordance with regulation 48(1);

"EEA State" means a State which is a Contracting Party to the EEA Agreement;

"European Economic Area" means the European Economic Area created by the Agreement on the European Economic Area signed at Oporto on 2nd May 1992(**g**), as adjusted by the Protocol signed at Brussels on 17th March 1993(**h**) ("the EEA Agreement");

"harmonised standard" means—

(a) a technical specification adopted, on a mandate from the European Commission, by the European Committee for Standardisation or the European Committee for

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(**a**) OJ No. L. 189, 20.7.1990, p.17.
(**b**) Council Directive 90/385/EEC has been amended by Council Directive 93/42/EEC (OJ No. L. 169, 12.7.1993, p.1) and Council Directive 93/68/EEC (OJ No. L 220, 30.8.1993, p.1).
(**c**) OJ No. L 169, 12.7.1993, p.1.
(**d**) Council Directive 93/42/EEC has been amended by Directive 98/79/EC (OJ No. L 331, 7.12.1998, p.1), Directive 2000/70/EC (OJ No. L 313, 13.12.2000, p.22) and Directive 2001/104/EC (OJ No. L 6, 10.1.2002, p.50).
(**e**) OJ No. L 331, 7.12.1998, p.1.
(**f**) OJ No. L 311, 28.11.2001, p.67.
(**g**) OJ No. L 1, 3.1.1994, p.3.
(**h**) OJ No. L 1, 3.1.1994, p.572.

Electrotechnical Standardisation, or by both of those bodies, in accordance with Directive 98/34/EC of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations(**a**), pursuant to the general guidelines on co-operation between the Commission and the said Committees signed on 13th November 1984; or

(b) a monograph of the European Pharmacopoeia (in particular any monograph on surgical sutures and the interaction between medicinal products and materials used in medical devices containing medicinal products),

the reference number of which has been published in the Official Journal of the European Communities;

"intended for clinical investigation" means—

(a) in relation to an active implantable medical device, that it is intended for use by a medical specialist when conducting clinical investigations of that device;

(b) in relation to any other medical 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—

(a) in relation to an active implantable medical device, the use for which it is intended and for which it is suited according to the data supplied by the manufacturer in the instructions relating to it;

(b) in relation to any other medical device, the use to which the device is intended according to the data supplied by the manufacturer on the labelling, the instructions for use and/or the promotional materials;

"*in vitro* diagnostic medical device" means a medical device which—

(a) is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination; and

(b) is intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information—

(i) concerning a physiological or pathological state,

(ii) concerning a congenital abnormality,

(iii) to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients, or

(iv) to monitor therapeutic measures,

and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for *in vitro* diagnostic examination;

"manufacturer" means—

(a) the person with responsibility 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; or

(b) any other 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, apart from a person who assembles or adapts devices already on the market to their intended purpose for an individual patient;

"medical device" means 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

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(**a**) OJ No. L 204, 21.7.1998, p.37; amended by Directive 98/48/EC (OJ No. L 217, 5.8.1998, p.18).

(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,

and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device;

"the Medical Devices Directives" means Directive 90/385, Directive 93/42 and Directive 98/79;

"medical specialist" means a registered medical practitioner who has a qualification as, or is undergoing training intended to lead to qualification as, a specialist;

"medicinal product" has the meaning given in article 1.2 of Directive 2001/83;

"Mutual Recognition Agreements" means the agreements, listed in Schedule 2, concluded between the European Community and States which are not part of the European Community on matters including the conditions under which each Party will accept or recognise the results of the conformity assessment procedures undertaken by the other Party's designated bodies;

"national standard" means a technical specification adopted by a Member State of the Community which transposes, and corresponds to, a harmonised standard;

"notified body" means a body authorised in accordance with Part V of the Medical Devices Directives to carry out tasks of a notified body or the importing Party under the Medical Devices Directives or the Mutual Recognition Agreements in respect of a conformity assessment procedure;

"placing on the market" means, in relation to a medical 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—

(a) in relation to an active implantable medical device, the making available of the device to a registered medical practitioner for implantation;

(b) in relation to any other medical device, the first making available of the device in the Community to a final user, including where a device is used in a professional context for the purposes of medical analysis without being marketed;

"relevant essential requirements", in relation to a medical device, means the essential requirements set out in Annex 1 of Directive 90/385, Annex I of Directive 93/42 or Annex I of Directive 98/79 which apply to it, but 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;

"specimen receptacle" means a medical device which (whether vacuum-type or not) is specifically intended by its manufacturer to be used for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination;

"stable derivatives device" means a medical device that contains human blood, blood products, plasma or blood cells of human origin, and which incorporates, as an integral part, a substance which—

(a) if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of article 1.10 of Directive 2001/83; and

(b) is liable to act upon the human body with action ancillary to that of the device;

"supply", in relation to a medical device, means—

(a) the supply of, or the offer or agreement to supply, the device; or

(b) the exposure or possession for supply of the device;

"third country conformity assessment body" means a body in a State which is not part of the European Community that is designated in accordance with the Mutual Recognition Agreements to carry out tasks of a notified body under the conformity assessment procedures set out in the Medical Devices Directives; and

"UK notified body" shall be construed in accordance with regulation 45.

(2) In these Regulations, unless the context otherwise requires, a reference—

(a) to a numbered regulation, Part or Schedule is to the regulation or Part of, or the Schedule to, these Regulations bearing that number;

(b) in a regulation to a numbered or lettered paragraph is to the paragraph of that regulation bearing that number or letter; and

(c) in a paragraph to a numbered or lettered sub-paragraph is to the sub-paragraph in that paragraph bearing that number or letter.

Scope of these Regulations

3. These Regulations shall not apply to—

(a) medicinal products governed by Directive 2001/83 (including medicinal products derived from human blood or human plasma governed by Title X of Directive 2001/83);

(b) human blood, human blood products, plasma or blood cells of human origin;

(c) devices that incorporate, at the time of placing on the market, human blood, blood products, plasma or blood cells of human origin, except for stable derivatives devices;

(d) transplants or tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin;

(e) 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;

(f) cosmetic products governed by Council Directive 76/768/EEC(**a**), as amended(**b**); or

(g) products whose principal intended purpose is such that they fall under Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment(**c**), as amended(**d**).

Transitional provisions

4.—(1) Part II shall not be applied before 1st July 2004 in respect 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(**e**).

(2) Part II shall not be applied—

(a) before 10th January 2007 in respect of a stable derivatives device placed on the market without a CE marking, if the device satisfies the requirements of the laws of that part of the United Kingdom in which it is placed on the market as in force on 10th January 2002; or

(b) before 10th January 2009 in respect of a stable derivatives device put into service without a CE marking, if the device satisfies the requirements of the laws of that part of the United Kingdom in which it is placed on the market as in force on 10th January 2002.

(3) Part IV shall not be applied before 7th December 2003 in respect of a device placed on the market which is—

(a) an *in vitro* diagnostic medical device without a CE marking; or

(b) a device for performance evaluation and the manufacturer or his authorised representative does not indicate, directly or indirectly, that it is a device which is subject to the provisions of these Regulations,

if the device satisfies the requirements of the laws of that part of the United Kingdom in which it is placed on the market as in force on 7th December 1998.

(**a**) OJ No. L 262, 27.9.1976, p.169.
(**b**) Council Directive 76/768/EEC was amended for the twenty-sixth time by Commission Directive 2000/41/EC (OJ No. L 145, 20.6.2000, p.25).
(**c**) OJ No. L 399, 30.12.1989, p.18.
(**d**) Council Directive 89/686/EEC has been amended by Council Directive 93/68/EEC (OJ No. L 220, 30.8.1993, p.1), Council Directive 93/95/EEC (OJ No. L 276, 9.11.1993, p.11) and Council Directive 96/58/EC (OJ No. L 236, 18.9.1996, p.44).
(**e**) S.I. 1993/2360.

(4) Part IV shall not be applied before 7th December 2005 in respect of a device put into service which is—

(a) an *in vitro* diagnostic medical device without a CE marking; or

(b) a device for performance evaluation and the manufacturer or his authorised representative does not indicate, directly or indirectly, that it is a device which is subject to the provisions of these Regulations,

if the device satisfies the requirements of the laws of that part of the United Kingdom in which it is put into service as in force on 7th December 1998.

PART II

General Medical Devices

Interpretation of Part II

5.—(1) In this Part, unless the context otherwise requires—

"accessory" means an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by its manufacturer;

"custom-made device" means a relevant device that is—

(a) 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) 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;

"relevant device" shall be construed in accordance with regulation 6;

"single-use combination product" means a product which comprises a medical device and medicinal product forming a single integral product which is intended exclusively for use in the given combination and which is not reusable; and

"system or procedure pack" has the same meaning as in article 12 of Directive 93/42.

(2) In this Part, unless the context otherwise requires, a reference to a numbered article or Annex is to the article or Annex of Directive 93/42 bearing that number.

Scope of Part II

6. The requirements of this Part in respect of relevant devices apply in respect of medical devices (including stable derivatives devices), accessories to such devices, single-use combination products, and systems and procedure packs, other than—

(a) active implantable medical devices and accessories to such devices;

(b) *in vitro* diagnostic medical devices and accessories to such devices; and

(c) devices that come within the scope of Directive 93/42 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, and

(i) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it, and

(ii) the manufacturer chooses to follow the set of arrangements in the other Directive.

Classification of general medical devices

7.—(1) For the purposes of this Part and Part VI, devices are classified as belonging to Class I, IIa, IIb or III in accordance with the classification criteria set out in Annex IX of Directive 93/42.

(2) In the event of a dispute between a manufacturer and a notified body over the classification of a device, the matter shall be referred to the Secretary of State, who shall determine the classification of the device in accordance with the classification criteria set out in Annex IX of Directive 93/42.

Essential requirements for general medical devices

8.—(1) Subject to regulation 12, no person shall place on the market or put into service a relevant device unless that device meets those essential requirements set out in Annex I which apply to it.

(2) Subject to regulation 12, no person shall supply a relevant device—

(a) if that supply is also a placing on the market or putting into service of that device; or

(b) in circumstances where that device has been placed on the market or put into service,

unless that device meets those essential requirements set out in Annex I which apply to it.

Determining compliance of general medical devices with relevant essential requirements

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

(2) 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.

(3) In the case of a relevant device which is being or 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—

(i) such instructions are in English or another Community language, and

(ii) if the instructions are not in English, any packaging, label or promotional literature carries a clear statement in English stating the language in which the instructions are given.

(4) A relevant 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 it does not comply with that requirement.

(5) A custom-made device—

(a) in respect of which the conditions specified in Annex VIII are satisfied; and

(b) 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.

(6) Where, in accordance with Section 2.1 of Annex VIII, a manufacturer of a custom-made device, or his authorised representative, has indicated that specified essential requirements have not been fully met, and has given proper grounds as to why they have not been fully met, those specified essential requirements are no longer to be treated as relevant essential requirements for that device.

(7) A device intended for clinical investigation in respect of which—

(a) the conditions specified in Annex VIII are satisfied;

(b) notice has been given under regulation 16(1); and

(c) either—

(i) no notice has been given under regulation 16(4) within the period of 60 days there referred to, or

(ii) notice has been given under regulation 16(5),

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.

(8) A single-use combination product shall be taken to comply with the relevant essential requirements if the medical device which forms part of that product only complies with the requirements set out in Annex I of Directive 93/42 that relate to safety and performance, unless the medicinal product which forms part of that product is liable to act on the human body with action ancillary to that of the medical device, in which case the single-use combination product must comply with all the relevant essential requirements which apply to it.

CE marking of general medical devices

10.—(1) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless, where practical and appropriate, that device or its sterile pack bears a CE marking which—

(a) meets the requirements set out in Annex XII;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(2) Subject to regulations 12 and 14, no person shall supply a relevant device unless, where practical and appropriate, that device or its sterile pack bears a CE marking which—

(a) meets the requirements set out in Annex XII;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless a CE marking, meeting the requirements set out in Annex XII, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for the device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(4) Subject to regulations 12 and 14, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless a CE marking, meeting the requirements set out in Annex XII, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for the device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(5) No person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

(a) a relevant device or its sterile pack;

(b) the instructions for use for a relevant device; or

(c) any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the CE marking or which reduces the visibility or the legibility of the CE marking.

CE marking of general medical devices that come within the scope of more than one Directive

11. Where a relevant device comes within the scope of Directive 93/42 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, no person shall affix a CE marking to the device unless the relevant requirements of the other Directive are also satisfied, except where—

(a) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it;

(b) the manufacturer chooses to follow the set of arrangements in Directive 93/42;

(c) the marking of the device indicates that the device only satisfies the set of arrangements chosen by the manufacturer; and

(d) the particulars of Directive 93/42, as published in the Official Journal of the European Communities, are given in the documents, notices or instructions accompanying the device.

Exemptions from regulations 8 and 10

12.—(1) A relevant device or a single use combination product being shown at a trade fair, exhibition, demonstration or similar gathering is not being placed on the market or put into service if a visible sign clearly indicates that the device or product cannot be marketed or put into service until it complies with the requirements of Directive 93/42 or these Regulations.

(2) Regulation 10 shall not apply to a custom-made device or a device intended for clinical investigation.

(3) Regulation 10 shall not apply to a relevant device which is a system or procedure pack, unless—

(a) the system or procedure pack incorporates a medical device which does not bear a CE marking; or

(b) the chosen combination of medical devices is not compatible in view of their original intended use.

(4) Regulation 10 shall not apply to single-use combination products, unless the medicinal product which forms part of that product is liable to act on the human body with action ancillary to that of the medical device which forms part of that product.

(5) Regulations 8 and 10 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a CE marking, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

Procedures for affixing a CE marking to general medical devices

13.—(1) A relevant device falling within Class I may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by Annex VII;

(b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 93/42 which apply to it; and

(c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

(2) A relevant device falling within Class IIa may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex II, excluding Section 4 of that Annex, or

(ii) Annex VII, together with Annex IV, V or VI;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and

(c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

(3) A relevant device falling within Class IIb may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex II, excluding Section 4 of that Annex, or

(ii) Annex III, together with Annex IV, V or VI;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and

(c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

(4) A relevant device falling within Class III may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex II, or

(ii) Annex III, together with Annex IV or V;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and

(c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

Procedures for systems and procedure packs, and for devices to be sterilised before use

14.—(1) Subject to paragraph (3), no person shall supply a system or procedure pack (if that supply is also a placing on the market, or if that supply is of a system or procedure pack that has been placed on the market) unless—

(a) the medical devices in that system or procedure pack are for use within their intended purpose and within the limits of use specified by their manufacturer;

(b) the person who places or has placed it on the market has drawn up a declaration that—

(i) he has verified the mutual compatibility of the medical devices in that system or procedure pack in accordance with the manufacturers' instructions, and he has carried out his operations in accordance with these instructions,

(ii) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers, and

(iii) his production of the system or procedure pack is subjected to appropriate methods of internal control and inspection,

and that declaration is true at the time it is made and continues to be true.

(2) Subject to paragraph (3), no person shall supply—

(a) a system or procedure pack which was sterilised before being placed on the market; or

(b) a relevant device (including a system or procedure pack) which is designed by its manufacturer to be sterilised before use,

(if that supply is also a placing on the market, or if that supply is of a device that has been placed on the market) unless the person who places, or who has placed, the device on the market satisfies the conditions set out in paragraph (4).

(3) Paragraphs (1) and (2)(a) shall only apply to a system or procedure pack if, by virtue of regulation 12(3), regulation 10 does not apply to that system or procedure pack.

(4) The conditions referred to in paragraph (2) are that the person shall—

(a) fulfil the obligations imposed by either Annex IV, Annex V or Annex VI that relate to the obtaining of sterility; and

(b) if the device has been sterilised, make a written declaration that sterilisation has been carried out in accordance with the manufacturer's instructions.

(5) Where a conformity assessment procedure is carried out in respect of a relevant device (including a device which is a system or procedure pack) pursuant to this regulation—

(a) no person shall affix a CE marking to that device as a result of that procedure; and

(b) no person shall supply that device (if that supply is also a placing on the market, or if that supply is of a device that has been placed on the market) unless it is 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 declarations referred to in paragraph (1)(b) and (4)(b) shall be kept available for the Secretary of State by the person responsible for placing the product on the market for a period of five years.

Procedures for custom-made general medical devices

15. No person shall supply a custom-made device (if that supply is also a placing on the market, or if that supply is of a custom-made device that has been placed on the market) unless its manufacturer or his authorised representative—

(a) has drawn up a statement containing the information required by Sections 1, 2 and 2.1 of Annex VIII;

(b) has undertaken 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 Directive 93/42; and

(c) takes 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; and

(d) keeps available for the Secretary of State, for a minimum period of five years, the information contained in the statement referred to in paragraph (a) and in the undertaking referred to in paragraph (b).

Procedures for general medical devices for clinical investigations

16.—(1) Subject to paragraph (2), no person shall supply a relevant device (if that supply is also a making available of the device) for the purposes of a clinical investigation in the United Kingdom unless, before he does so, the manufacturer of the device or his authorised representative has given at least 60 days prior notice in writing to the Secretary of State of the intended investigation, in the form of—

(a) subject to paragraph (3), the statement required by Sections 1 and 2 of Annex VIII; and

(b) an undertaking to keep available for the Secretary of State the documentation referred to in Section 3.2 of Annex VIII for a minimum period of five years.

(2) Paragraph (1) shall not apply in respect of an intended clinical investigation of a relevant device that bears a CE marking otherwise than in breach of regulation 13, unless the aim of the intended investigation is to determine whether the device may be used for a purpose other than that in respect of which it was CE marked in accordance with regulation 13.

(3) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex VIII need not be provided to the Secretary of State at least 60 days prior to the intended investigation, but if it is not provided at least 60 days prior to the intended investigation, it must be provided to the Secretary of State by the manufacturer or his authorised representative as soon as it becomes available.

(4) If, within 60 days of the formal acceptance by the Secretary of State of the notice in writing given pursuant to paragraph (1), the Secretary of State gives written notice to the manufacturer or authorised representative (whichever gave the notice pursuant to paragraph (1)) that, on grounds of public health or public policy, the relevant device should not be made available for the purposes of the intended investigation, no person shall supply the relevant device (if that supply is also a making available of the device) for those purposes.

(5) The Secretary of State may, in respect of notice in writing given by a manufacturer or his authorised representative pursuant to paragraph (1), give written notice to the manufacturer or his authorised representative—

(a) that the relevant device may be made available for the purposes of the intended investigation; or

(b) if the ethics committee opinion required under Section 2.2 of Annex VIII is not available, that the relevant device may be made available for the purposes of the intended investigation once a favourable opinion in respect of the investigational plan for the intended investigation has been delivered by the committee.

(6) A written notice pursuant to paragraph (5) may—

(a) where appropriate be given subject to conditions imposed by the Secretary of State, which are to be included in the notice;

(b) at any time be withdrawn on grounds of public health or public policy by the Secretary of State.

(7) Where a written notice pursuant to paragraph (5) in respect of a relevant device has been withdrawn by the Secretary of State—

(a) further clinical use of the relevant device in the investigation is prohibited; and

(b) no person shall supply that relevant device for the purposes of the investigation (if that supply is also a making available of the device),

unless the Secretary of State issues a further written notice pursuant to that paragraph stating that the relevant device may again be made available for the purposes of the investigation.

(8) The manufacturer of a relevant device intended for clinical investigation to which paragraph (1) applies, or his authorised representative, shall—

(a) take all necessary measures to ensure that the manufacturing process for the relevant device produces devices manufactured in accordance with the documentation referred to in the first paragraph of Section 3.2 of Annex VIII;

(b) authorise the assessment, including audit where necessary, of the effectiveness of the measures which he takes pursuant to this regulation; and

(c) keep the information contained in the statement and the undertaking referred to in paragraph (1) for a minimum period of five years.

(9) The grounds of public health or public policy referred to in paragraph (4) or (6)(b) are met, amongst other reasons, if—

(a) the manufacturer or his authorised representative does not authorise an assessment by the Secretary of State, whether by means of an audit, an inspection or otherwise, of the effectiveness of the measures referred to in paragraph (8); 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).

(10) No person shall conduct a clinical investigation of a relevant device—

(a) otherwise than in accordance with Annex X; and

(b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (6)(a),

and if a clinical investigation is conducted in respect of a relevant device, the manufacturer of that device or his authorised representative shall keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex X.

Manufacturers etc. and conformity assessment procedures for general medical devices

17.—(1) A manufacturer of a relevant device or, where applicable, his authorised representative who is required to follow, or follows or has followed a conformity assessment procedure set out in Directive 93/42 shall observe the manufacturer's obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, his authorised representative shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 93/42 at an intermediate stage of manufacture of the device.

(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—

(a) 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, where appropriate, upon the importer referred to in Section 13.3(a) of Annex I;

(b) Section 2 of Annex VII shall fall upon the person who places on the market the device to which the documentation relates.

UK notified bodies and the conformity assessment procedures for general medical devices

18.—(1) A UK notified body which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

(a) take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 93/42 at an intermediate stage of manufacture of the device;

(b) 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; and

(c) lay down, by common accord with the manufacturer or his authorised representative, the time limits for completion of the assessment and verification operations referred to in Annex II to IV.

(2) Where a UK notified body takes a decision in accordance with Annex II or III, they shall specify the period of validity of the decision, which initially shall be for a period of not more than five years.

(3) Where a UK notified body and a manufacturer or his authorised representative have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or his authorised representative, extend the period of validity of the decision for further periods of up to five years, each such period commencing on the expiry of the previous period.

Registration of persons placing general medical devices on the market

19.—(1) Subject to paragraph (6), for the purpose of enabling the Secretary of State to exercise his functions under these Regulations, any person to whom this paragraph applies shall—

(a) inform the Secretary of State of the address of his registered place of business; and

(b) supply the Secretary of State with a description of each category of device concerned.

(2) Paragraph (1) applies to—

(a) a manufacturer with a registered place of business in the United Kingdom who, under his own name, places on the market in the United Kingdom a relevant device which is a Class 1 device or a custom-made device, other than a system or procedure pack which is not CE marked; and

(b) a person with a registered place of business in the United Kingdom who sterilises before use relevant devices designed by their manufacturer to be sterilised before use.

(3) Subject to paragraph (6), for the purpose of enabling the Secretary of State to exercise his functions under these Regulations, any person with a registered place of business in the United Kingdom who places a device mentioned in paragraph (2) on the market in the United Kingdom on behalf of a manufacturer who does not have a registered place of business in the Community or in a State which is a Party to an Association Agreement shall inform the Secretary of State of—

(a) the address of his registered place of business;

(b) the category of device; and

(c) in the case of an authorised representative of the manufacturer, the fact that he is the manufacturer's authorised representative, and he shall furnish the Secretary of State with sufficient evidence that he is an authorised representative of the manufacturer.

(4) Subject to paragraph (6), for the purpose of enabling the Secretary of State to exercise his functions under these Regulations, any person with a registered place of business in the United Kingdom who places a system or procedure pack which is not CE marked on the market in the United Kingdom, or who sterilises systems or procedure packs before they are placed on the market, 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 which are included in any such system or procedure pack in a manner sufficient to identify them.

(5) Subject to paragraph (6), for the purpose of enabling the Secretary of State to exercise his functions under these Regulations, any person with a registered place of business in the United Kingdom who places a relevant device which is a Class IIb or III device on the market in the United Kingdom (including the authorised representative of a manufacturer of a Class IIb or III device who does not have a registered place of business in the Community or in a State which is a Party to an Association Agreement) shall, if the Secretary of State so requests, supply the Secretary of State with all data allowing for the identification of the device together with the label and the instructions for use for when the device is put into service within the United Kingdom.

(6) Registration under this regulation is not required if—

(a) the device or pack was first placed on the market in a State which is a Party to an Association Agreement (if that Agreement contains measures relating to the mutual recognition of the results of conformity assessment undertaken in respect of that device); and

(b) the manufacturer or his authorised representative has already registered with the competent authorities of that State.

PART III

Active Implantable Medical Devices

Interpretation of Part III

20.—(1) In this Part, unless the context otherwise requires—

"custom-made device" means an active implantable medical device that is—

(a) manufactured specifically in accordance with a medical specialist's written prescription which gives, under his responsibility, specific characteristics as to its design; and

(b) intended to be used only for a particular patient; and

"relevant device" shall be construed in accordance with regulation 21.

(2) In this Part, unless the context otherwise requires, a reference to a numbered article or Annex is to the article or Annex of Directive 90/385 bearing that number.

Scope of Part III

21. The requirements of this Part in respect of relevant devices apply in respect of active implantable medical devices and accessories to such devices, except for devices that come within the scope of Directive 90/385 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, and

(a) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it; and

(b) the manufacturer chooses to follow the set of arrangements in the other Directive.

Essential requirements for active implantable medical devices

22.—(1) Subject to regulation 26, no person shall place on the market or put into service a relevant device unless that device meets those essential requirements set out in Annex 1 which apply to it.

(2) Subject to regulation 26, no person shall supply a relevant device—

(a) if that supply is also a placing on the market or putting into service of that device; or

(b) in circumstances where that device has also been placed on the market or put into service,

unless that device meets those essential requirements set out in Annex 1 which apply to it.

Determining compliance of active implantable medical devices with relevant essential requirements

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

(2) Any—

(a) determination that a relevant device complies with any of the essential requirements set out in paragraphs 1 to 5 of Annex 1; and

(b) evaluation of side effects or undesirable effects for the purposes of determining whether or not a relevant device complies with any of the essential requirements,

shall be based in particular on clinical data, the adequacy of which is based on the collation of scientific literature or the results of clinical investigations referred to in paragraph 1 of Annex 7, and any determination as to whether or not a relevant device complies with any other essential requirements may be based on such data.

(3) In the case of a relevant device which is being or has been put into service—

(a) the essential requirements specified in paragraph 14 of Annex 1 are complied with only if the particulars there specified are in English (whether or not they are also in another language and whether or not the device is for professional use); and

(b) the essential requirements specified in paragraph 13 of Annex 1, so far as they relate to instructions required for the operation of a device in paragraph 15 of Annex 1, are complied with only if—

(i) the instructions are in English or another Community language, and

(ii) if the instructions are not in English, any packaging, label or promotional literature carries a clear statement in English stating the language in which the instructions are given.

(4) A relevant 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.

(5) A custom-made device in respect of which the conditions specified in Annex 6 are satisfied and which is accompanied by the statement referred to in paragraph 1 of Annex 6 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.

(6) A device intended for clinical investigation in respect of which—

(a) the conditions specified in Annex 7 are satisfied;

(b) notice has been given under regulation 29(1); and

(c) either—

(i) no notice has been given under regulation 29(3) within the period of 60 days there referred to, or

(ii) notice has been given under regulation 29(4),

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 of active implantable medical devices

24.—(1) Subject to regulation 26, no person shall place on the market or put into service a relevant device unless that device or its sterile pack bears a CE marking which—

(a) meets the requirements set out in Annex 9;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(2) Subject to regulation 26, no person shall supply a relevant device unless that device or its sterile pack bears a CE marking which—

(a) meets the requirements set out in Annex 9;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulation 26, no person shall place on the market or put into service a relevant device unless a CE marking, meeting the requirements set out in Annex 9, appears on—

(a) where appropriate, any sales packaging for that device; and

(b) the instructions for use for the device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(4) Subject to regulation 26, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless a CE marking, meeting the requirements set out in Annex 9, appears on—

(a) where appropriate, any sales packaging for that device; and

(b) the instructions for use for the device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(5) No person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

(a) a relevant device or its sterile pack;

(b) the instructions for use for a relevant device; or

(c) where appropriate, any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the CE marking or which reduces the visibility or the legibility of the CE marking.

CE marking of active implantable medical devices that come within the scope of more than one Directive

25. Where a relevant device comes within the scope of Directive 90/385 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, no person shall affix a CE marking to the device unless the relevant requirements of the other Directive are also satisfied, except where—

(a) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it;

(b) the manufacturer chooses to follow the set of arrangements in Directive 90/385;

(c) the marking of the device indicates that the device only satisfies the set of arrangements chosen by the manufacturer; and

(d) the particulars of Directive 90/385, as published in the Official Journal of the European Communities, are given in the documents, notices or instructions accompanying the device, and in a manner in which those particulars are accessible without it being necessary to destroy the packaging which keeps the device sterile.

Exemptions from regulations 22 and 24

26. —(1) A relevant device being shown at a trade fair, exhibition, demonstration or similar gathering is not being placed on the market or put into service if a visible sign clearly indicates that the device or product cannot be marketed or put into service until it complies with the requirements of Directive 90/385 or these Regulations.

(2) Regulation 24 shall not apply to a custom-made device or a device intended for clinical investigation.

(3) Regulations 22 and 24 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a CE marking, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

Procedures for affixing a CE marking to active implantable medical devices

27. A relevant device may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex 2, or

(ii) Annex 3, together with Annex 4 or 5;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 90/385 that apply to it; and

(c) ensures that the device meets the provisions of Directive 90/385 which apply to it.

Procedures for custom-made active implantable medical devices

28. No person shall supply a custom-made device (if that supply is also a placing on the market, or if that supply is of a custom-made device that has been placed on the market) unless its manufacturer or his authorised representative—

(a) has drawn up the statement containing the information required by Section 2.1 of Annex 6;

(b) has undertaken to keep available for the Secretary of State the documentation referred to in Section 3.1 of Annex 6;

(c) takes 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 6; and

(d) keeps available for the Secretary of State the information contained in the statement referred to in paragraph (a) and in the undertaking referred to in paragraph (b).

Procedures for active implantable medical devices for clinical investigations

29.—(1) No person shall supply a relevant device (if that supply is also a making available of the device) for the purposes of a clinical investigation in the United Kingdom unless, before he does so, the manufacturer of the device or his authorised representative has given at least 60 days prior notice in writing to the Secretary of State of the intended investigation, in the form of—

(a) subject to paragraph (2), the statement required by Section 2.2 of Annex 6; and

(b) an undertaking to keep available for the Secretary of State the documentation referred to in Section 3.1 and 3.2 of Annex 6.

(2) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex 6 need not be provided to the Secretary of State at least 60 days prior to the intended investigation, but if it is not provided at least 60 days prior to the intended investigation, it must be provided to the Secretary of State by the manufacturer or his authorised representative as soon as it becomes available.

(3) If, within 60 days of the formal acceptance by the Secretary of State of the notice in writing given pursuant to paragraph (1), the Secretary of State gives written notice to the manufacturer or authorised representative (whichever gave the notice pursuant to paragraph (1)) that, on grounds of public health or public policy, the relevant device should not be made available for the purposes of the intended investigation, no person shall supply the relevant device (if that supply is also a making available of the device) for those purposes.

(4) The Secretary of State may, in respect of notice in writing given by a manufacturer or his authorised representative pursuant to paragraph (1), give written notice to the manufacturer or his authorised representative—

(a) if the ethics committee opinion required under Section 2.2 of Annex 6 is favourable, that the relevant device may be made available for the purposes of the intended investigation; or

(b) if the ethics committee opinion required under Section 2.2 of Annex 6 is not available, that the relevant device may be made available for the purposes of the intended investigation once a favourable opinion in respect of the investigational plan for the intended investigation has been delivered by the committee.

(5) A written notice pursuant to paragraph (4) may—

(a) where appropriate be given subject to conditions imposed by the Secretary of State, which are to be included in the notice;

(b) at any time be withdrawn on grounds of public health or public policy by the Secretary of State.

(6) Where a written notice pursuant to paragraph (4) in respect of a relevant device has been withdrawn by the Secretary of State—

(a) further clinical use of the relevant device in the investigation is prohibited; and

(b) no person shall supply that relevant device for the purposes of the investigation (if that supply is also a making available of the device),

unless the Secretary of State issues a further written notice pursuant to that paragraph stating that the relevant device may again be made available for the purposes of the investigation.

(7) The manufacturer of a relevant device intended for clinical investigation to which paragraph (1) applies, or his authorised representative, shall—

(a) 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, and the first paragraph of Section 3.2, of Annex 6;

(b) keep available for the Secretary of State the information contained in the statement and the undertaking referred to in paragraph (1); and

(c) authorise the assessment, including audit where necessary, of the effectiveness of the measures which he takes pursuant to this regulation.

(8) The grounds of public health or public policy referred to in paragraphs (3) and (5)(b) are met, amongst other reasons, if—

(a) the manufacturer or his authorised representative does not authorise an assessment by the Secretary of State, whether by means of an audit, an inspection or otherwise, of the effectiveness of the measures referred to in paragraph (7); 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).

(9) No person shall conduct a clinical investigation of a relevant device—

(a) otherwise than in accordance with Annex 7; and

(b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (5)(a),

and if a clinical investigation is conducted in respect of a relevant device, the manufacturer of that device or his authorised representative shall keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex 7.

Manufacturers etc. and conformity assessment procedures for active implantable medical devices

30.—(1) A manufacturer of a relevant device or, where applicable, his authorised representative who is required to follow, or follows or has followed a conformity assessment procedure set out in Directive 90/385 shall observe the manufacturer's obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, his authorised representative shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 90/385 at an intermediate stage of manufacture of the device.

UK notified bodies and the conformity assessment procedures for active implantable medical devices

31.—(1) A UK notified body which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

(a) take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 90/385 at an intermediate stage of manufacture of the device; and

(b) lay down, by common accord with the manufacturer or his authorised representative, the time limits for completion of the assessment and verification operations referred to in Annex 2 or 3.

(2) Where a UK notified body takes a decision in accordance with Annex 2 or 3, they shall specify the period of validity of the decision, which initially shall be for a period of not more than five years.

(3) Where a UK notified body and a manufacturer or his authorised representative have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or his authorised representative, extend the period of validity of the decision for further periods of up to five years, each such period commencing on the expiry of the previous period.

PART IV

In Vitro Diagnostic Medical Devices

Interpretation of Part IV

32.—(1) In this Part, unless the context otherwise requires—

"accessory" means an article intended specifically by its manufacturer to be used together with an *in vitro* diagnostic medical device to enable that device to be used in accordance with its intended purpose, which is not—

(a) itself an *in vitro* diagnostic medical device;

(b) an invasive sampling medical device; or

(c) a medical device which is directly applied to the human body for the purpose of obtaining a specimen;

"calibration and control material" means any substance, material or article intended by its manufacturer either to establish measurement relationships or to verify the performance characteristics of a relevant device in conjunction with the intended use of that device;

"common technical specification" means a technical specification for a relevant device referred to in a list in Annex II which has been adopted in accordance with the procedure set out in article 7(2) and published in the Official Journal of the European Communities;

"device for self-testing" means an *in vitro* diagnostic medical device which is intended by its manufacturer to be able to be used by a member of the public in a home environment; and

"relevant device" shall be construed in accordance with regulation 33(1);

(2) In this Part, unless the context otherwise requires, a reference to a numbered article or Annex is to the article or Annex of Directive 98/79 bearing that number.

Scope of Part IV

33.—(1) The requirements of this Part in respect of relevant devices apply in respect of *in vitro* diagnostic medical devices and accessories to such devices, except for—

(a) products manufactured and used within the same health institution and either on the premises of their manufacture or on premises in the immediate vicinity without having been transferred to another legal entity; and

(b) devices that come within the scope of Directive 98/79 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, and

(i) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it, and

(ii) the manufacturer chooses to follow the set of arrangements in the other Directive.

(2) The requirements of this Part in respect of devices for performance evaluation do not apply in respect of—

(a) products manufactured and used only within the same health institution and either on the premises of their manufacture or on premises in the immediate vicinity without having been transferred to another legal entity; and

(b) devices that come within the scope of Directive 98/79 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, and

(i) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it, and

(ii) the manufacturer chooses to follow the set of arrangements in the other Directive.

Essential requirements for *in vitro* diagnostic medical devices

34.—(1) Subject to regulation 39, no person shall place on the market or put into service a relevant device unless that device meets those essential requirements set out in Annex I which apply to it.

(2) Subject to regulation 39, no person shall supply a relevant device—

(a) if that supply is also a placing on the market or putting into service of that device; or

(b) in circumstances where that device has been placed on the market or put into service,

unless that device meets those essential requirements set out in Annex I which apply to it.

Determining compliance of *in vitro* diagnostic medical devices with relevant essential requirements

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

(2) In order to meet the essential requirements set out in Section 8 of Part B of Annex I, the information to be provided under that Section must be in English if the device may reach a final user in the United Kingdom, unless—

(a) the Secretary of State, to the extent that Directive 98/79 allows him to do so, has authorised the use of another Community language or more than one other Community language; or

(b) the relevant device is a device for self-testing, in which case the instructions for use and the label must include a translation into the official language of any member State of the Community in which the device reaches a final user.

(3) A relevant device shall be presumed to comply with an essential requirement if it conforms as respects that requirement to a relevant national standard.

(4) A relevant device shall be treated as complying with an essential requirement in respect of which there is an applicable common technical specification only if it is in conformity with that specification or, if for duly justified reasons the manufacturer has not complied with that specification, an equivalent or higher specification.

CE marking of *in vitro* diagnostic medical devices

36.—(1) Subject to regulation 39, no person shall place on the market or put into service a relevant device unless, where practical and appropriate, that device bears a CE marking which—

(a) meets the requirements set out in Annex X;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(2) Subject to regulation 39, no person shall supply a relevant device unless, where practical and appropriate, that device bears a CE marking which—

(a) meets the requirements set out in Annex X;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulation 39, no person shall place on the market or put into service a relevant device unless a CE marking, meeting the requirements set out in Annex X, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for that device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(4) Subject to regulation 39, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless a CE marking, meeting the requirements set out in Annex X, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for that device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(5) Subject to regulation 39, no person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

(a) a relevant device;

(b) the instructions for use for a relevant device; or

(c) any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the CE marking or which reduces the visibility or the legibility of the CE marking.

CE marking of *in vitro* diagnostic medical devices that come within the scope of more than one Directive

37. Where a relevant device comes within the scope of Directive 98/79 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, no person shall affix a CE marking to the device unless the relevant requirements of the other Directive are satisfied, except where—

(a) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it;

(b) the manufacturer chooses to follow the set of arrangements in Directive 98/79;

(c) the marking of the device indicates that the device only satisfies the set of arrangements chosen by the manufacturer; and

(d) the particulars of Directive 98/79, as published in the Official Journal of the European Communities, are given in the documents, notices or instructions accompanying the device.

In vitro **diagnostic medical devices not ready for use**

38. Subject to regulation 39, no person shall—

(a) put into service a relevant device;

(b) supply a relevant device—

(i) if that supply is also a putting into service of that device, or

(ii) in circumstances where that device has been placed on the market or put into service,

which is not ready for use.

Exemptions from regulations 34, 36 and 38

39.—(1) A relevant device being shown at a trade fair, exhibition, scientific gathering or technical gathering is not being placed on the market or put into service if—

(a) the device is not used on any specimen taken from the participants; and

(b) a visible sign clearly indicates that the device cannot be marketed or put into service until it complies with the requirements of Directive 98/79 or these Regulations.

(2) Regulations 34, 36 and 38 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a CE marking, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

Procedures for affixing a CE marking to *in vitro* diagnostic medical devices

40.—(1) A relevant device other than a device referred to in the lists in Annex II or a device for self-testing may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by Sections 1 to 5 of Annex III;

(b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 98/79 which apply to it; and

(c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

(2) A relevant device which is a device for self-testing but which is not referred to in a list in Annex II may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Sections 1 to 6 of Annex III,

(ii) Annex IV, or

(iii) Annex V and either Annex VI or Annex VII;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 98/79 which apply to it; and

(c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

(3) A relevant device referred to in List A in Annex II may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex IV, or

(ii) Annexes V and VII;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 98/79 which apply to it; and

(c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

(4) A relevant device referred to in List B in Annex II may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex IV,

(ii) Annexes V and VI, or

(iii) Annexes V and VII;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 98/79 which apply to it; and

(c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

Manufacturers etc. and conformity assessment procedures for *in vitro* diagnostic medical devices

41.—(1) A manufacturer of a relevant device or, where applicable, his authorised representative who is required to follow, or follows or has followed a conformity assessment procedure set out in Directive 98/79 shall observe the manufacturer's obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, his authorised representative shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 98/79 at an intermediate stage of manufacture of the device.

(3) A manufacturer or, where applicable, his authorised representative shall, in respect of any relevant device which the manufacturer has placed on the market or put into service, keep available for inspection by the Secretary of State—

(a) the declaration of conformity for that device;

(b) the technical documentation referred to in Annexes III to VIII relating to that device; and

(c) the decisions, reports and certificates of notified bodies relating to that device,

for a period ending five years after the manufacture of the last product.

(4) A person who in the course of manufacturing relevant devices or devices for performance evaluation removes, collects, or uses tissues, cells or substances of human origin shall, in the course of removing, collecting or using those tissues, cells or substances act in accordance with the principles laid down in the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine(**a**).

(5) Until the European databank referred to in article 12 has been established, the manufacturer or, where applicable, his authorised representative shall, in respect of any relevant device which the manufacturer has placed on the market in the United Kingdom, provide the Secretary of State with the data referred to in article 12(1)(a), and that data shall be provided in English.

UK notified bodies and the conformity assessment procedures for *in vitro* diagnostic medical devices

42.—(1) A UK notified body which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

(a) take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 98/79 at an intermediate stage of manufacture of the device;

(b) 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 before 7th June 2000; and

(c) lay down, by common accord with the manufacturer or his authorised representative, the time limits for completion of the assessment and verification operations referred to in Annexes III to VII.

(2) Where a UK notified body takes a decision in accordance with Annex III, IV, or V, they shall specify the period of validity of the decision, which, initially, shall be a period of not more than 5 years.

(3) Where a UK notified body and a manufacturer or his authorised representative have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or his authorised representative, extend the period of validity of the decision for further periods of up to 5 years, each such period commencing on the expiry of the previous period.

Devices for performance evaluation

43. No person shall supply a device for performance evaluation (if that supply is also a making available of the device) unless the manufacturer or his authorised representative—

(a) has drawn up a statement containing the information required by Section 2 of Annex VIII and keeps that statement available for the Secretary of State for a minimum period of five years after the end of the performance evaluation;

(b) ensures that—

(i) the device conforms with the documentation mentioned in the said section 2, and

(ii) the relevant requirements of the Directive are complied with as respects that device; and

(c) undertakes to keep available, and keeps available, for the Secretary of State, for a minimum period of five years after the end of the performance evaluation, 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.

(**a**) Council of Europe (ETS No. 164), Orviedo, 4.4.1997.

Registration of manufacturers etc. of *in vitro* diagnostic medical devices and devices for performance evaluation

44.—(1) Subject to paragraph (3), for the purpose of enabling the Secretary of State to exercise his functions under these Regulations, any person to whom this paragraph applies shall give the Secretary of State the following information—

(a) the address of his registered place of business in the United Kingdom;

(b) in the case of an authorised representative, sufficient evidence that he is the authorised representative of the manufacturer;

(c) in relation to a new relevant device, a statement indicating that the device is a new relevant device, and for the purposes of this regulation a device is a "new relevant device" if—

(i) there has been no such device continuously available on the Community market during the previous three years for the relevant analyte or other parameter, or

(ii) use of the device involves analytical technology not continuously used in connection with a given analyte or other parameter on the Community market during the previous three years;

(d) in relation to a new relevant device, if requested by the Secretary of State (such a request only being permissible within two years from the date on which the Secretary of State was notified that the device was a new relevant device, and on justified grounds), a report relating to the experience gained with the device subsequent to its being placed on the market;

(e) if the device wholly or partly consists of reagents, reagent products or calibration and control materials, appropriate information in terms of common technological characteristics and/or analytes;

(f) if the device does not wholly or partly consist of reagents, reagent products or calibration and control materials, the appropriate indications;

(g) in relation to devices referred to in a list in Annex II and devices for self-testing—

(i) all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex I, the outcome of performance evaluation pursuant to Annex VIII, and certificates, and

(ii) if requested by the Secretary of State, the labelling and the instructions for use for when the device is placed on the market or put into service within the United Kingdom; and

(h) in relation to devices for performance evaluation which relate either to devices referred to in a list in Annex II or to devices for self- testing, all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex I,

and shall notify him of any significant change to that information including discontinuation of the placing on the market of the device.

(2) Paragraph (1) applies to—

(a) a manufacturer with a registered place of business in the United Kingdom who places a relevant device on the market, or who makes available a device for performance evaluation, under his own name; and

(b) a person with a registered place of business in the United Kingdom who places a relevant device on the market in the United Kingdom, or who makes available a device for performance evaluation, on behalf of a manufacturer who does not have a registered place of business in the Community or in a State which is a Party to an Association Agreement as his authorised representative.

(3) Registration under this regulation is not required if—

(a) the device was first placed on the market in another Member State of the Community or in a State which is a Party to an Association Agreement (if that Agreement contains measures relating to the mutual recognition of the results of conformity assessment undertaken in respect of that device); and

(b) the manufacturer or his authorised representative has already registered with the competent authorities of that other State.

Designation etc. of UK notified bodies

45.—(1) The Secretary of State may designate for the purposes of article 11 of Directive 90/385, article 16 of Directive 93/42 or article 15 of Directive 98/79 any corporate or other body as a body which is to carry out any of the tasks of a notified body, and, if he so designates a body (referred to in these Regulations as a "UK notified body"), he shall designate the tasks which it is to carry out.

(2) A body may be designated under paragraph (1) as a body which is to carry out tasks of a notified body only if—

(a) in so far as it is to be designated as a body which is to carry out tasks included in Directive 90/385, it is a body in respect of which the criteria for the designation of notified bodies set out in Annex 8 of that Directive are met;

(b) in so far as it is to be designated as a body which is to carry out tasks included in Directive 93/42, it is a body in respect of which the criteria for the designation of notified bodies set out in Annex XI of that Directive are met;

(c) in so far as it is to be designated as a body which is to carry out tasks included in Directive 98/79, it is a body in respect of which the criteria for the designation of notified bodies set out in Annex IX of that Directive are met; and

(d) in so far as it needs to be able to fulfil the functions of an importing Party arising out of the Mutual Recognition Agreements, it is able to do so.

(3) The Secretary of State may refuse to designate a body under paragraph (1) if it fails to pay any fee payable under Part VI in connection with an application for designation.

(4) The Secretary of State may vary the tasks that a UK notified body may carry out, and if he does, those varied tasks will be the tasks which it is designated to carry out.

(5) The Secretary of State may place a restriction in relation to, or withdraw, any designation of a body under paragraph (1) if—

(a) the body so requests;

(b) he considers that it is no longer a body in respect of which the applicable criteria for designation set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42 or Annex IX of Directive 98/79 are met; or

(c) he considers that the body is not capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil,

and the Secretary of State may also withdraw any designation of a body under paragraph (1) if it fails to pay any fee payable under Part VI.

(6) Before—

(a) effecting a variation under paragraph (4); or

(b) restricting or withdrawing a designation under paragraph (5),

otherwise than at the notified body's request, the Secretary of State shall give to the notified body an opportunity to make representations to him 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 criteria set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42 or Annex IX of Directive 98/79 are met as respects the tasks which the body wants to carry out, or carries out, or for the purposes of deciding whether or not a body is capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, 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 undertaking any task in relation to that manufacturer,

and may take into account for the purposes of his decision the results of any such inspection and any refusal to afford him such facilities or assistance as he may reasonably require in order to carry out any such inspection.

(8) The Secretary of State may request that a UK notified body supply to him any or all relevant information and documents, including budgetary documents, necessary—

(a) to enable him to verify that the body meets the criteria set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42, or Annex IX of Directive 98/79; or

(b) for the purposes of deciding whether or not the body is capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil,

and the body shall supply to him any and all relevant information or documents so requested.

Choice of notified bodies and conformity assessment bodies

46. Where a conformity assessment procedure involves the intervention of a notified body, including work which may be carried out by a third country conformity assessment body, the manufacturer of a device or his authorised representative may apply to any notified body or third country conformity assessment body to carry out tasks under that procedure which are within the framework of tasks which the body is designated to carry out.

General matters relating to UK notified bodies

47.—(1) A UK notified body to which an application has been made by a manufacturer or his authorised representative to perform the functions of a notified body under a conformity assessment procedure set out in the Medical Devices Directives shall perform those functions, in accordance with the requirements of the procedure, if those functions are within the framework of tasks which the body is designated to carry out.

(2) Where a manufacturer or his authorised representative has supplied information or data to a UK notified body in the course of a conformity assessment procedure, that body may, where duly justified, require the manufacturer to provide any additional information or data which it considers necessary for the purposes of that procedure.

(3) The information, data and correspondence that a manufacturer or his authorised representative supplies to a notified body in the course of a conformity assessment procedure set out in the Medical Devices Directives shall, if the notified body is within the United Kingdom, be in English or some other Community language acceptable to the notified body concerned.

(4) A UK notified body shall, as respects a medical device which it has assessed other than an active implantable medical device, inform all other notified bodies and the Secretary of State of—

(a) all certificates suspended or withdrawn; and

(b) on request, all certificates issued or refused,

and shall also make available to them, on request, any or all additional relevant information.

(5) Where a UK notified body finds, as respects a medical device which it has assessed other than an active implantable medical device, that—

(a) the applicable requirements of the Medical Devices Directives have not been met or are no longer met; or

(b) a certificate issued by it should not have been issued,

it may (having regard in particular to the principle of proportionality and the ability of the manufacturer to take appropriate corrective measures) suspend or withdraw the certificate issued in respect of that device or place restrictions on it, and in such cases, or in cases where the notified body is aware of circumstances in which the Secretary of State may need to take action pursuant to regulation 61, the notified body shall inform the Secretary of State thereof.

(6) The Secretary of State may request that a UK notified body supply to him any information and documents that the Secretary of State may, having regard to the terms of the Mutual Recognition Agreements, need to supply to a Party to the Mutual Recognition Agreements, and the body shall supply to him any and all information or documents so requested.

(8) A UK notified body shall provide conformity assessment bodies with all the information it is required to provide to those bodies under the Mutual Recognition Agreements.

Designation etc. of EC conformity assessment bodies

48.—(1) The Secretary of State may designate for the purposes of the Mutual Recognition Agreements any corporate or other body as a body which is to carry out any of the tasks of a European Community conformity assessment body, and, if he so designates a body (referred to in these Regulations as an "EC CAB"), he shall designate the tasks which it is to carry out.

(2) A body may be designated under paragraph (1) as a body which is to carry out tasks of an EC CAB only if the Secretary of State considers that the body is capable of fulfilling the functions of an EC CAB arising out of the Mutual Recognition Agreements which it needs to be able to fulfil.

(3) The Secretary of State may refuse to designate a body under paragraph (1) if it fails to pay any fee payable under Part VI in connection with an application for designation.

(4) The Secretary of State may vary the tasks that an EC CAB may carry out, and if he does, those varied tasks will be the tasks which it is designated to carry out.

(5) The Secretary of State may place a restriction in relation to, or withdraw, any designation of a body under paragraph (1) if—

(a) the body so requests; or

(b) he considers that the body is not capable of fulfilling the functions of an EC CAB arising out of the Mutual Recognition Agreements which it needs to be able to fulfil,

and the Secretary of State may also withdraw any designation of a body under paragraph (1) if it fails to pay any fee payable under Part VI.

(6) Before—

(a) effecting a variation under paragraph (4); or

(b) restricting or withdrawing a designation under paragraph (5),

otherwise than at the EC CAB's request, the Secretary of State shall give to the EC CAB an opportunity to make representations to him 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 capable of fulfilling the functions of an EC CAB arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, 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 undertaking any task in relation to that manufacturer,

and may take into account for the purposes of his decision the results of any such inspection and any refusal to afford him such facilities or assistance as he may reasonably require in order to carry out any such inspection.

(8) The Secretary of State may request that an EC CAB supply to him any or all relevant information and documents, including budgetary documents, necessary for the purposes of deciding whether or not the body is capable of fulfilling the functions of an EC CAB arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, and the body shall supply to him any and all relevant information or documents so requested.

Fees charged by UK notified bodies and EC conformity assessment bodies

49.—(1) A UK notified body or EC CAB may charge a fee in accordance with paragraphs (2), (3) and (4) for anything done in, or in connection with—

(a) in the case of a UK notified body, performing the functions of a notified body or an importing Party under the Medical Devices Directives or the Mutual Recognition Agreements in respect of a conformity assessment procedure set out in the Medical Devices Directives; and

(b) in the case of an EC CAB, performing the functions of an EC CAB arising out of the Mutual Recognition Agreements in respect of a conformity assessment procedure for a medical device.

(2) Except as provided for 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 UK notified body or EC CAB charging the fee is a body the activities of which are carried on for profit, the fee 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 UK notified body or EC CAB may require payment of the 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.

Products incorrectly marked with a notified body or conformity assessment body number

50.—(1) No person shall—

(a) affix a notified body or conformity assessment body number to a medical device if that body has not carried out an assessment in respect of that device for that person;

(b) supply a medical device (if that supply is also a placing on the market, or if that supply is of a device which has been placed on the market) which has affixed to it a notified body or conformity assessment body number if that body—

(i) has not carried out an assessment in respect of that device, or has not carried out that assessment for the person responsible for placing the device on the market, or

(ii) has had its designation as a notified body or conformity assessment body withdrawn.

(2) No person shall provide information comprising a notified body or conformity assessment body number on a medical device, the instructions for use for a medical device, or the sales packaging for a medical device if that device—

(a) is being or has been placed on the market; and

(b) the notified body or conformity assessment body—

(i) has not carried out an assessment in respect of that device, or has not carried out that assessment for the person responsible for placing the device on the market, or

(ii) has had its designation as a notified body or conformity assessment body withdrawn.

(3) Where the sectoral annex on medical devices in a Mutual Recognition Agreement under which a conformity assessment body was designated states that the annex does not apply to devices of a particular class or description, no person may supply a medical device of that class or description bearing the number of that conformity assessment body (if that supply is also a placing on the market or putting into service or is of a device that has been placed on the market or put into service) unless—

(a) an assessment has been carried out on that device for the person responsible for placing it on the market or putting it into service by a notified body; and

(b) the device bears the notified body number of that notified body.

(4) For the purposes of this regulation, a notified body shall be taken to have carried out an assessment in respect of a device if it has endorsed a report prepared by a third country conformity assessment body in respect of that device.

Products incorrectly marked with a CE marking

51.—(1) No person shall—

(a) affix the CE marking for a medical device to a product which is not a medical device; or

(b) supply a product (if that supply is also a placing on the market, or if that supply is of a product which has been placed on the market) which has affixed to it the CE marking for a medical device if that product is not a medical device.

(2) No person shall provide information comprising a CE marking for a medical device on a product, the instructions for use for a product, or the sales packaging for a product if the product is not a medical device.

PART VI

Fees charged by the Secretary of State

Interpretation of Part VI

52.—(1) In this Part, unless the context otherwise requires—

"Group A device" means a Class I medical device, a Class IIa medical device, or a Class IIb medical device which is neither an implantable device nor a long term invasive medical device;

"Group B device" means a Class IIb medical device which is either an implantable medical device or a long term invasive medical device, or a Class III medical device, or an active implantable medical device; and "half day" means a period of three and a half hours.

(2) For the purposes of this Part, medical devices are classified as being implantable or long term invasive medical devices in accordance with the definitions set out in Section 1 of Annex IX of Directive 93/42, and in the event of a dispute over the classification of a device, the Secretary of State shall determine the classification of the device in accordance with the definitions set out in Section 1 of Annex IX of Directive 93/42.

Fees in connection with the registration of devices and changes to registration details

53. Any person required to supply the Secretary of State with any information under regulation 19 or 44 shall, in respect of the processing of that information with regard to the possible registration of that person by the Secretary of State or possible changes to his registration details, pay to the Secretary of State a fee of £70, and that fee—

(a) shall be payable when the information is supplied by that person to the Secretary of State; and

(b) shall accompany that information when it is supplied.

Fees payable in connection with the designation etc. of UK notified bodies

54.—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 45 as a notified body shall, in connection with that application for designation, pay to the Secretary of State—

(a) if it is the second or subsequent such application and the application is being made only to address the grounds for rejection of a previous application, a fee of £650; or

(b) in all other cases, a fee of £2,600.

(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 45(4) of the tasks that the body may carry out shall, in connection with that application for a variation, pay to the Secretary of State a fee of £1,300.

(3) Where, pursuant to regulation 45(7) the Secretary of State inspects premises for the purposes of deciding whether or not a body is one in respect of which the criteria set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42 or Annex IX of Directive 98/79 are met, or for the purposes of deciding whether or not a body is capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, the body shall pay to the Secretary of State—

(a) in respect of an initial inspection pursuant to regulation 45(7)(a), a fee of £3,200, plus—

(i) an amount for time spent by a member of staff undertaking a site visit at a rate, for the time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate, for the time spent travelling to and from the site, of £51.39 per hour,

(ii) the actual costs of travel, accommodation and subsistence, and

(iii) out of pocket expenses;

(b) in respect of any other inspection pursuant to regulation 45(7)(a), a fee of £2,600, plus—

(i) an amount for time spent by a member of staff undertaking a site visit at a rate, for the time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate, for the time spent travelling to and from the site, of £51.39 per hour,

(ii) the actual costs of travel, accommodation and subsistence, and

(iii) out of pocket expenses; and

(c) in respect of an inspection pursuant to regulation 45(7)(b), a fee of £2,600, plus—

(i) an amount for time spent by a member of staff undertaking a site visit at a rate, for the time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate, for the time spent travelling to and from the site, of £51.39 per hour,

(ii) the actual costs of travel, accommodation and subsistence, and

(iii) out of pocket expenses.

(4) A fee under this regulation—

(a) in connection with an application for designation under regulation 45(1) or a variation under regulation 45(4)—

(i) shall be payable when the application to the Secretary of State is made, and

(ii) shall accompany the application when it is made;

(b) in connection with an inspection pursuant to regulation 45(7), shall be payable within one month of receipt by the body of a written notice from the Secretary of State requiring payment of the fee.

Fees payable in connection with the designation etc. of EC conformity assessment bodies

55.—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 48 as an EC CAB shall, in connection with that application for designation, pay to the Secretary of State—

(a) if it is the second or subsequent such application and the application is being made only to address the grounds for rejection of a previous application, a fee of £650; or

(b) in all other cases, a fee of £2,600.

(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 48(4) of the tasks that the body may carry out shall, in connection with that application for a variation, pay to the Secretary of State a fee of £1,300.

(3) Where, pursuant to regulation 48(7) the Secretary of State inspects premises for the purposes of deciding whether or not a body is capable of fulfilling the functions of an EC CAB arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, the body shall pay to the Secretary of State—

(a) in respect of an initial inspection pursuant to regulation 48(7)(a), a fee of £3,200, plus—

(i) an amount for time spent by a member of staff undertaking a site visit at a rate, for the time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate, for the time spent travelling to and from the site, of £51.39 per hour,

(ii) the actual costs of travel, accommodation and subsistence, and

(iii) out of pocket expenses;

(b) in respect of any other inspection pursuant to regulation 48(7)(a), a fee of £2,600, plus—

(i) an amount for time spent by a member of staff undertaking a site visit at a rate, for the time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate, for the time spent travelling to and from the site, of £51.39 per hour,

(ii) the actual costs of travel, accommodation and subsistence, and

(iii) out of pocket expenses; and

(c) in respect of an inspection pursuant to regulation 48(7)(b), a fee of £2,600, plus—

(i) an amount for time spent by a member of staff undertaking a site visit at a rate, for the time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate, for the time spent travelling to and from the site, of £51.39 per hour,

(ii) the actual costs of travel, accommodation and subsistence, and

(iii) out of pocket expenses.

(4) A fee under this regulation—

(a) in connection with an application for designation under regulation 48(1) or a variation under regulation 48(4)—

(i) shall be payable when the application to the Secretary of State is made, and

(ii) shall accompany the application when it is made;

(b) in connection with an inspection pursuant to regulation 48(7), shall be payable within one month of receipt by the body of a written notice from the Secretary of State requiring payment of the fee.

Fees payable in relation to clinical investigation notices

56.—(1) Subject to paragraph (2), any person required to give the Secretary of State notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) shall, in respect of the consideration by the Secretary of State of the information that the person is required to submit, pay to the Secretary of State—

(a) if, as regards that device, it is the second or subsequent occasion on which the person has given the Secretary of State notice of an intended clinical investigation, and the changes from the immediately preceding notice are limited to addressing the grounds on which the Secretary of State has refused or withdrawn permission to hold a clinical investigation—

(i) a fee, if the device is a Group A device, of £1,600, or

(ii) a fee, if the device is a Group B device, of £2,100; or

(b) in all other cases—

(i) a fee, if the device is a Group A device, of £2,200, or

(ii) a fee, if the device is a Group B device, of £3,000.

(2) Except where paragraph (3) applies, no fee shall be payable in respect of a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) where the manufacturer or his authorised representative has previously given such notice in relation to that device.

(3) A fee shall be payable where the investigational plan which forms part of the statement accompanying the notice differs from the plan submitted with the immediately preceding notice in that it includes—

(a) a change to address the grounds on which the Secretary of State has refused or withdrawn permission to hold a clinical investigation;

(b) a change to the number of patients or devices forming the basis of the proposed trial;

(c) a change or extension in the indications for use of the device or to the purpose or objectives of the trial;

(d) a change in any of the materials used in the device that come into direct contact with the human body if the new materials are not known to be biocompatible; or

(e) a change in the design of the device involving a novel feature not previously tested, being a change that has a direct effect on a vital physiological function.

(4) A fee under this regulation—

(a) shall be payable when the notice to which it relates is given to the Secretary of State; and

(b) shall accompany that notice when it is given.

Unpaid fees

57. All unpaid sums due by way of, or on account of, any fees payable under this Part are recoverable as debts due to the Crown.

Waivers, reductions and refunds

58.—(1) The Secretary of State may—

(a) waive payment of any fee or reduce any fee or part of a fee otherwise payable under this Part;

(b) refund the whole or part of any fee paid pursuant to this Part.

(2) Without prejudice to the generality of paragraph (1), where—

(a) a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) is withdrawn within the period of 7 days beginning with the date of its receipt by the Secretary of State; or

(b) an application for designation as—

(i) a notified body under regulation 45(1), or

(ii) an EC CAB under regulation 48(1),

(other than one submitted only to address the grounds of rejection of a previous application) is withdrawn within the period of 21 days beginning with the date of its receipt by the Secretary of State,

the fee payable shall be reduced to fifty per cent of the fee otherwise payable in respect of such notice or application, and any excess already paid shall be refunded.

PART VII

General, Enforcement and Miscellaneous

Interpretation of Part VII

59. In this Part, unless the context otherwise requires—

"registrable device" means a device in respect of which, in accordance with the Medical Devices Directives, registration is required with the competent authorities of a Member State or (where appropriate) a State which is a Party to an Association Agreement;

"relevant device" means a device that is a "relevant device" for the purposes of Part II, III or IV.

Designation etc. of authorised representatives

60.—(1) Where these Regulations place any obligation, other than an obligation referred to in regulation 17(3), on a manufacturer of a device or his authorised representative, and the manufacturer does not have a registered place of business in the Community or (where appropriate) in a State which is a Party to an Association Agreement, no person shall—

(a) place that device on the market; or

(b) supply that device in circumstances where it has been placed on the market,

unless the manufacturer of the device has designated an authorised representative to perform that obligation, but once the manufacturer has designated an authorised representative to perform that obligation, that obligation shall be performed by the authorised representative (although in all other cases it shall be performed by the manufacturer).

(2) If the manufacturer of a registrable device does not have a registered place of business in the Community or (where appropriate) in a State which is a Party to an Association Agreement, no person shall place that device on the market or supply that device in circumstances where it has been placed on the market unless its manufacturer has designated an authorised representative as—

(a) the person responsible for marketing the device in the Community; and

(b) the person responsible for registering in respect of that device with—

(i) the Secretary of State in accordance with regulation 19 or, as the case may be, 44, or

(ii) the competent authorities of another Member State or (where appropriate) a State which is a Party to an Association Agreement.

(3) Where a manufacturer of a registrable device, or of a relevant device that is not registrable, has designated an authorised representative as the person responsible for marketing the device within the Community, that authorised representative—

(a) may be proceeded against as a person placing the device on the market for the purposes of these Regulations;

(b) in relation to any supply of the device to a person within the United Kingdom after it has been placed on the market, may be proceeded against as a person supplying the device after it has been placed on the market, unless that supply is due to an act of another person established in the Community or in a State which is a Party to an Association Agreement.

(4) If a person claims or purports to act as an authorised representative of a manufacturer of a device, the Secretary of State may, for the purposes of enabling the Secretary of State to exercise his functions under these Regulations, require that person to furnish the Secretary of State with sufficient evidence that he is an authorised representative of the manufacturer.

Enforcement etc.

61.—(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, notices or otherwise) and for the purposes of section 38 of that Act (disclosure of information) as safety regulations as defined in that Act(**a**), 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(**b**).

(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 relevant devices or devices for performance evaluation, and that duty is transferred to the Secretary of State.

(3) Paragraph (2) does 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(**c**), and accordingly but subject to paragraph (4), 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) The powers of an enforcement authority to serve restriction notices under regulation 63 are only exercisable by the Secretary of State.

(5) 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 the 1987 Act in respect of a device to which paragraph (3) applies;

(b) any application made by it under section 16 of the 1987 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 the 1987 Act.

(6) In respect of an offence committed under section 12 of the 1987 Act relating to a contravention of these Regulations—

(a) a magistrates' court in England or Wales may try any information laid within 12 months from the time when the offence was committed;

(b) a magistrates' court in Northern Ireland may hear and determine any complaint made within 12 months from the time when the offence was committed; and

(c) in Scotland, summary proceedings for the offence may be commenced at any time within 12 months from the time when the offence was committed.

(7) 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 goods considered unsafe by the Secretary of State), 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 relevant devices being or not being non-conforming devices.

(8) In paragraph (7), "non-conforming devices" means—

(a) relevant devices which, whether or not the Secretary of State considers them unsafe, are devices with or that require a CE marking which he considers to be devices—

(i) which do not conform as respects a relevant essential requirement; or

(ii) to which a CE marking has or should have been applied following a conformity assessment procedure set out in the Medical Devices Directives, and—

(**a**) *See* section s 11(1) and 45(1) of that Act.
(**b**) *See* section 45(1) of that Act.
(**c**) *See* section 11(7) of that Act.

(aa) the manufacturer or his authorised representative has failed to comply with his obligations under that procedure, or

(bb) they do not conform to the design or type described in any certificate granted as a result of that procedure; or

(b) devices for performance evaluation which, whether or not the Secretary of State considers them unsafe, are devices in respect of which there is a failure to comply with these Regulations.

Compliance notices

62.—(1) 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 a relevant device or a device for performance evaluation is a device in respect of which there is a failure to comply with these Regulations, 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 the device is a device in respect of which there is failure to comply with these Regulations and the reasons for that suspicion;

(c) specifying the relevant provision of these Regulations and, where applicable, any relevant provision of the Medical Devices Directives;

(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 specified provision 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 in 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 or the 1987 Act in respect of that device or any device of the same type supplied by that person.

(2) Where an enforcement authority serves a notice referred to in paragraph (1), 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 (1)(d) has expired and unless, in relation to the alleged failure to comply with these Regulations, at the expiry of that period the person on whom the notice was served has failed to comply with its requirements.

(3) The notice referred to in paragraph (1) may include directions as to the measures to be taken by the person on whom the notice is served to secure compliance with the provisions of these Regulations, including different ways of securing compliance, and any such directions are requirements of the notice for the purposes of paragraph (2).

Restriction notices

63.—(1) Subject to paragraph (2), where an enforcement authority is of the opinion that it is necessary to restrict the availability of—

(a) a particular medical device, a particular accessory to such a device or a particular device for performance evaluation; or

(b) medical devices, accessories to such devices or devices for performance evaluation of a particular class or description,

in order to protect the health or safety of any individual or of individuals of any class or description, they may serve on any person a notice ("a restriction notice") including such directions restricting the availability of that device or those devices as appear to them to be necessary in order to protect the health or safety of that individual or individuals of that class or description.

(2) Paragraph (1) shall not apply to active implantable medical devices or to accessories to such devices.

(3) The enforcement authority responsible for serving a restriction notice may, in appropriate circumstances, withdraw the notice.

(4) A direction in a restriction notice that has not been withdrawn by an enforcement authority or set aside by an order of a court or a sheriff is a safety provision for the purposes of sections 14 to 17 of the 1987 Act.

(5) Where, in the course of or as a result of enforcement action in relation to a suspected contravention of a direction in a restriction notice, an application has been made to a magistrates' court or a sheriff—

(a) under section 15 of the 1987 Act (appeals against suspension notices), the court or the sheriff may make an order setting aside the restriction notice as well as any suspension notice served in respect of the suspected contravention of the direction;

(b) under section 16 or 17 of the 1987 Act (which relate to forfeiture of goods), the court or the sheriff may make an order setting aside the restriction notice,

if the court or the sheriff is satisfied that the restriction notice should not have been served or should be withdrawn.

(6) Any person aggrieved by an order made under paragraph (5), or by a decision not to make such an order, may appeal against that order or decision, and that appeal shall be treated in the same way as any other appeal that has been or could be made against any other decision or order of the court in the proceedings under section 15, 16 or 17 of the 1987 Act which led to the decision or order relating to the restriction notice being made.

Notification of decisions etc.

64.—(1) Any decision taken by a UK notified body, the Secretary of State or any other enforcement authority pursuant to these Regulations to withdraw a device from the market, or to prevent or restrict a device being placed on the market, put into service or made available, shall be notified without delay to the person responsible for marketing the device, placing it on the market, putting it into service or making it available, and that person shall be informed—

(a) of the grounds on which the decision is based;

(b) of the legal remedies available to that person and of any time limits which apply to their exercise; and

(c) if the applicant was not entitled under the 1987 Act to make representations in respect of the decision, that the decision maker will, on request, review the decision and in the course of so doing will give him or his authorised representative an opportunity to make representations in respect of the decision.

(2) Except in cases where urgent action is justified (in particular by public health requirements), if a UK notified body, the Secretary of State or any other enforcement authority is considering making a decision referred to in paragraph (1), they or he shall give the manufacturer or his authorised representative an opportunity to make representations to them or him before the decision is taken.

Centralised systems of records etc.

65. The Secretary of State shall perform, as respects the United Kingdom, the functions of the Member State under article 8 of Directive 90/385, article 10 of Directive 93/42 and article 11(1) to (3) of Directive 98/79.

Revocations

66. The following provisions are hereby revoked—

(a) the Active Implantable Medical Devices Regulations 1992(**a**);

(b) the Medical Devices Regulations 1994(**b**);

(c) the Active Implantable Medical Devices (Amendment and Transitional Provisions) Regulations 1995(**c**);

(d) the Medical Devices Fees Regulations 1995(**d**);

(e) the Medical Devices Fees (Amendment) Regulations 1997(**e**);

(**a**) S.I. 1992/3146.
(**b**) S.I. 1994/3017.
(**c**) S.I. 1995/1671.
(**d**) S.I. 1995/2487.
(**e**) S.I. 1997/694.

(f) the *In Vitro* Diagnostic Medical Devices Regulations 2000(**a**); and

(g) regulations 6 and 13 of the Medicines (Codification Amendments Etc.) Regulations 2002(**b**).

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
19th May 2002 Department of Health

We consent,

Tony McNulty
Nick Ainger
20th May 2002 Two of the Lords Commissioners of Her Majesty's Treasury

SCHEDULE 1

Regulation 2(1)

ASSOCIATION AGREEMENTS

1. The Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Hungary, of the other part, on Conformity Assessment and Acceptance of Industrial Products(**c**).

SCHEDULE 2

Regulation 2(1)

MUTUAL RECOGNITION AGREEMENTS

1. The agreement on mutual recognition in relation to conformity assessment certificates and markings between the European Community and Australia, initialled on 19th July 1996(**d**).

2. The agreement on mutual recognition in relation to conformity assessment between the European Union and New Zealand, initialled on 19th July 1996(**e**).

3. The agreement on mutual recognition between the European Community and Canada, signed in London on 14th May 1998(**f**).

4. The agreement on mutual recognition between the European Community and the United States of America, signed in London on 18th May 1998(**g**).

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations contain the legislative measures necessary for the implementation of three European Community Directives: Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, as amended; Council Directive 93/42/EEC concerning medical devices, as amended; and Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices ("the Medical Devices Directives"). They also contain the legislative measures necessary for the implementation, in relation to medical devices, of the agreements on mutual recognition between the European Community and Australia, New Zealand, Canada and the United States of America—and of the Association Agreement between the European Communities, and their Member States, and Hungary.

Part I contains introductory provisions. These include an interpretation provision (regulation 2), and provisions both limiting the scope of the application of the Regulations so that they only apply to products covered by the Medical Devices Directives (regulation 3) and

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(**a**) S.I. 2000/1315.
(**b**) S.I. 2002/236.
(**c**) OJ No. L 135, 17.5.2001, p.35.
(**d**) OJ No. L 229, 17.8.1998, p.3.
(**e**) OJ No. L 229, 17.8.1998, p.62.
(**f**) OJ No. L 280, 16.10.1998, p.3.
(**g**) OJ No. L 31, 4.2.1999, p.3.

delaying the application of provisions of the Regulations in relation to specific categories of medical devices, to take account of the transitional arrangements in the Medical Devices Directives (regulation 4).

Part II deals with the marketing of medical devices generally, but not with active implantable medical devices or *in vitro* diagnostic medical devices. Medical devices covered by this Part must generally meet the essential requirements set out in Annex I to Directive 93/42/EEC (regulations 8 and 9), and must be CE-marked according to the conformity assessment procedures set out in that Directive (regulations 10 and 13). There are exemptions for certain products (regulation 12), and special arrangements for products covered by more than one European Community Directive (regulation 11). There are also specific arrangements for systems and procedure packs, custom-made devices and devices intended for clinical investigations (regulations 14 to 16). Arising out of the conformity assessment procedures, there are specific obligations placed on manufacturers of devices or their authorised representatives (regulation 17), and on the notified bodies involved in carrying out assessments in respect of devices (regulation 18). Manufacturers of certain medical devices, or their authorised representatives, must register with the Secretary of State (regulation 19).

Part III deals with active implantable medical devices. Again, these can only be marketed if they meet specified essential requirements, set out in Directive 90/385/EEC (regulations 22 and 23), and are assessed under conformity assessment procedures (regulations 24 and 27). There are special arrangements for devices that come under more than one European Community Directive (regulation 25), and some exemptions from the scheme (regulation 26). Again, there are different procedures for custom-made devices and devices for clinical investigation (regulations 28 and 29). Specific obligations are imposed on manufacturers or their authorised representatives (regulation 30), and on notified bodies carrying out assessments in respect of the devices (regulation 31).

Part IV deals with *in vitro* diagnostic medical devices. These also must conform to the essential requirements set out in Directive 98/79/EC (regulations 33 and 34), and must be CE-marked according to one of the conformity assessment procedures set out in the Directive (regulations 36 and 40). There are again exemptions (regulation 39), and special arrangements for products caught by more than one European Community Directive (regulation 37). There are also special arrangements for devices for performance evaluation (regulation 43). Manufacturers or their authorised representatives have specific obligations relating to the conformity assessment procedures (regulation 41), and generally have to register (regulation 44). Notified bodies also have specific obligations relating to the conformity assessment procedures (regulation 42).

Part V contains general provisions relating to the designation of notified bodies within the United Kingdom (regulation 45). Companies may apply to any European Community notified body or third country conformity assessment body (the equivalent body under a Mutual Recognition Agreement) to carry out tasks under a conformity assessment procedure, if the task is within the framework of tasks that the body is designated to carry out (regulation 46). There are also provisions for designating conformity assessment bodies to carry out conformity assessment work for other Parties to Mutual Recognition Agreements (regulation 48). This Part also contains prohibitions on marking products with CE marks or with notified body or conformity assessment body numbers if they are not entitled to bear those markings (regulations 50 and 51).

Part VI sets out the fees charged by the Secretary of State in relation to work done pursuant to the Regulations. These include charges in connection with the registration of devices and changes to registration details (regulation 53), charges to UK notified bodies and EC Conformity Assessment Bodies (regulations 54 and 55), and fees payable in connection with clinical investigation notices (regulation 56). There are also arrangements for unpaid fees, waivers, reductions and refunds (regulations 57 and 58).

Part VII includes general matters, including the provisions relating to designation of authorised representatives and enforcement (regulations 60 to 64), and requirements to keep a centralised system of records (regulation 65). This Part also contains revocations of provisions that are superseded as a result of the coming into force of these Regulations (regulation 66).

A Regulatory Impact Appraisal and a Transposition Note in relation to the implementation of Directives 2000/70/EC and 2001/104/EC (the two most recent Directives amending Council Directive 93/42/EEC), have been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medical Devices Agency, Hannibal House, Elephant and Castle, London SE1 6TQ.

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E0857 6/2002 120857 19585