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STATUTORY INSTRUMENTS

2000 No. 1315

CONSUMER PROTECTION

The *In Vitro* Diagnostic Medical Devices Regulations 2000

Made - - - -	*11th May 2000*
Laid before Parliament	*15th May 2000*
Coming into force	*7th June 2000*

ARRANGEMENT OF REGULATIONS

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SCHEDULES

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:—

Citation and commencement

1. These Regulations may be cited as the *In Vitro* Diagnostic Medical Devices Regulations 2000 and shall come into force on 7th June 2000.

Interpretation

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

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

"the 1994 Regulations" means the Medical Devices Regulations 1994**(e)**;

"the 1995 Regulations" means the Medical Devices Fees Regulations 1995**(f)**;

"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;

"authorised representative" means a person established within the Community who, explicitly designated by the manufacturer (in accordance with regulation 13 or otherwise), acts for the manufacturer and may be addressed by authorities and bodies in the Community instead of the manufacturer;

"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;

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

"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;

(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.
(e) S.I. 1994/3017.
(f) S.I. 1995/2487; amended by S.I. 1997/694.

"the Community" means the European Community;

"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;

"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;

"the Directive" means Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices**(a)**;

"intended purpose" means the use for which a relevant 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" has the same meaning as the meaning given for "device" in the 1994 Regulations;

"notified body" means, in relation to any task, a body designated and notified in respect of that task in accordance with article 15 or under regulation 15;

"placing on the market" means, in relation to a relevant device, the first making available in return for payment or free of charge of a new or fully refurbished relevant device with a view to distribution, use, or both, on the Community market;

"putting into service" means, in relation to a relevant 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 device" shall be construed in accordance with regulation 3(1);

"relevant essential requirement" means, in relation to a relevant device, an essential requirement which, for the purposes of regulation 4, applies to it;

"relevant harmonised standard" means a technical specification adopted, on a mandate from the European Commission, by the European Committee for Standardisation or the

(a) O.J. No. L331, 7.12.1998, p. 1.

European Committee for 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;

"relevant national standard" means a standard transposing a relevant harmonised standard, the reference number of which has been published in the Official Journal of the European Communities;

"relevant notified body identification number" means, in relation to a relevant device, the identification number of the notified body responsible for implementation of the procedures set out in Annexes III, IV, VI and VII relating to assessment of that device by a notified body, that number being the identification number assigned to the notified body by the European Commission in accordance with article 15(1);

"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;

"supply", in relation to a device, means the supply of, or offer or agreement to supply, the device, or the exposure or possession for supply of the device;

"UK notified body" shall be construed in accordance with regulation 15(1).

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

(a) to a numbered regulation is to the regulation of 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;

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

(d) to a numbered article or Annex is to the article or Annex of the Directive bearing that number.

Scope of the Regulations

3.—(1) Subject to paragraph (3), the requirements of these Regulations in respect of relevant devices apply in respect of *in vitro* diagnostic medical devices and accessories to such devices, except for 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.

(2) Subject to paragraph (3), the requirements of these Regulations in respect of devices for performance evaluation do not apply in respect of 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.

(3) Restriction notices under regulation 19(4) may be served in respect of any *in vitro* diagnostic medical device, any accessory to such a device, or any device for performance evaluation.

Essential requirements for relevant devices

4.—(1) Subject to regulation 8, 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 8, 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.

(a) O.J. L204, 21.7.1998, p. 37; amended by Directive 98/48/EC (O.J. 217, 5.8.1998, p. 18).

(3) In determining which of the essential requirements in Annex I apply to a particular relevant device, account shall be taken of the intended purpose of the device.

(4) 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 when the device reaches the final user, unless—

(a) the Secretary of State, to the extent that the Directive 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 the member State in which the device reaches its final user.

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

(6) 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

5.—(1) Subject to regulation 8, no person shall place on the market, put into service or supply (if that supply is also a placing on the market or putting 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 the relevant notified body identification number, if there is a relevant notified body identification number for that device.

(2) Subject to regulation 8, no person shall place on the market, put into service or supply (if that supply is also a placing on the market or putting 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 the relevant notified body identification number, if there is a relevant notified body identification number for that device.

(3) Subject to regulation 8, 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 legibility of the CE marking.

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

6. Where a relevant device comes both within the scope of the Directive 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, which set of arrangements applies to it;

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

(c) whichever set of arrangements is chosen, the particulars of the other directive, as published in the Official Journal of the European Communities, are given in the documents, notices or instructions accompanying the device.

Relevant devices not ready for use

7. Subject to regulation 8, 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 4, 5 and 7

8.—(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 the Directive or these Regulations.

(2) Regulations 4, 5 and 7 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised 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.

Procedure for affixing a CE marking

9.—(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, having taken into account where appropriate the matters referred to in article 9(5), that the device meets the provisions of the Directive which apply to it; and

(c) ensures that the device meets the provisions of the Directive 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, having taken into account where appropriate the matters referred to in article 9(5), that the device meets the provisions of the Directive which apply to it; and

(c) ensures that the device meets the provisions of the Directive 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, having taken into account where appropriate the matters referred to in article 9(5), that the device meets the provisions of the Directive which apply to it; and

(c) ensures that the device meets the provisions of the Directive 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, having taken into account where appropriate the matters referred to in article 9(5), that the device meets the provisions of the Directive which apply to it; and

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

Supplemental provisions relating to conformity assessment procedures

10.—(1) Where a conformity assessment procedure set out in the Directive involves the intervention of a notified body, the manufacturer of a relevant device or his authorised representative may apply to any notified body to carry out tasks under that procedure which 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 notified body in the course of a conformity assessment procedure set out in the Directive, the notified body may, where duly justified, require the manufacturer or his authorised representative to provide any additional information or data which the notified body 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 Directive 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 manufacturer or, where applicable, his authorised representative who is required to follow, or follows or has followed a conformity assessment procedure set out in the Directive in respect of a relevant device, shall observe the manufacturer's obligations set out in that procedure that apply to him.

(5) 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.

(6) 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)**.

(7) 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

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

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.

CE marking of a product which is not a relevant device

11.—(1) No person shall—

(a) affix a CE marking for a relevant device to a product which is not a relevant device;

(b) place on the market or supply (if that supply is also a placing on the market) a product which has affixed to it a CE marking for a relevant device if that product is not a relevant device.

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

Devices for performance evaluation

12. A device for performance evaluation may be made available only if 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.

Designation of authorised representatives for registration purposes

13. A manufacturer without a registered place of business in the Community who, under his own name—

(a) places a relevant device on the market; or

(b) makes available a device for performance evaluation,

shall designate an authorised representative as the person responsible for performing the functions of an authorised representative referred to in regulation 14.

Registration of manufacturers etc. of devices

14. For the purpose of enabling the Secretary of State to exercise his functions under these Regulations, 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, or an authorised representative designated in accordance with regulation 13, 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, evidence 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 or 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;

(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.

Designation etc. of notified bodies

15.—(1) The Secretary of State may designate for the purposes of article 15 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 hereafter 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 it is a body in respect of which the criteria for the designation of notified bodies set out in Annex IX are met.

(3) The Secretary of State may refuse to designate a body under paragraph (1) if it fails to pay any fee payable under the 1995 Regulations**(a)** 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; or

(b) he considers that it is no longer a body in respect of which the criteria set out in Annex IX are met,

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 the 1995 Regulations.

(a) As amended by regulation 23 of, and Schedule 2 to, these Regulations.

(6) Before—

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

(b) withdrawing 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 IX are met as respects the tasks which it wants to carry out or carries out, the Secretary of State may arrange for the inspection of—

(a) any premises occupied, or plant or equipment used, in connection with the carrying out of any such task; or

(b) any premises occupied, or plant or equipment used, by a manufacturer where the body is a notified body undertaking any task in relation to that manufacturer,

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.

Functions of notified bodies

16.—(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 Directive shall perform those functions, if those functions are within the framework of tasks which the body is designated to carry out.

(2) A UK notified body shall 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.

(3) 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.

(4) 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 the decision, 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.

(5) A UK notified body shall, in carrying out a conformity assessment procedure for affixing the CE marking to a relevant device, take into account where appropriate the matters referred to in article 9(5).

(6) A UK notified body which is responsible for carrying out a conformity assessment procedure in connection with a relevant device shall, in doing so, take account of any relevant information relating to the characteristics and performance of that device, including in particular the results of any relevant tests and verification relating to that device already carried out before these Regulations come into force.

(7) A UK notified body shall 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.

(8) Where, as respects a relevant device, a UK notified body finds that—

(a) the applicable requirements of the Directive 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 18 or 19, the notified body shall inform the Secretary of State thereof.

(9) 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 to enable him to verify that the body meets the criteria set out in Annex IX, and the body shall supply to him the relevant information and documents so requested.

Fees charged by UK notified bodies

17.—(1) A UK notified body may charge a fee in accordance with paragraphs (2), (3) and (4) for anything done in, or in connection with, performing the functions of a notified body under a conformity assessment procedure set out in the Directive.

(2) Except as provided by paragraph (3), the fee charged in respect of anything done shall not exceed an amount which reasonably represents the cost incurred, or to be incurred, in doing it.

(3) Where the UK notified body charging the fee is a body the activities of which are carried on for profit, the fee for doing anything may include an amount representing a profit which is reasonable in the circumstances, having regard to—

(a) the character and extent of the work done or to be done by the notified body; and

(b) the commercial rate normally charged in respect of profit for that work or similar work.

(4) The UK notified body may require payment of a fee, or a reasonable estimate of the fee, in advance of carrying out the work in respect of which the fee is payable and as a condition of doing that work.

Enforcement etc.

18.—(1) Notwithstanding that they are made partly in exercise of powers other than those conferred by section 11 of the 1987 Act, these Regulations shall be regarded for all purposes relating to enforcement (whether by criminal proceedings or notices or otherwise) and for the purposes of section 38 of that Act (disclosure of information) as safety regulations as defined in that Act**(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, 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 relevant 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 19(4) 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) 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

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

relation to relevant goods which the Secretary of State considers are unsafe (as well as being exercisable in relation to such goods), and in relation to non-conforming devices, Schedule 2 to the 1987 Act shall have effect as if references to goods being unsafe or safe were references to relevant devices being or not being non-conforming devices.

(7) In paragraph (6), "non-conforming devices" means—

(a) relevant devices which, whether or not the Secretary of State considers then 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 Directive, and—

(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 relevant EC design-examination certificate or EC type-examination certificate; 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.

(7) The Secretary of State shall perform, as respects the United Kingdom, the functions of a member State under article 11(1) to (3).

Notice procedures

19.—(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;

(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 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 as are included are requirements of the notice for the purposes of paragraph (2).

(4) Where an enforcement authority is of the opinion that it is necessary to restrict the availability of—

(a) a particular *in vitro* diagnostic medical device, a particular accessory to such a device or a particular device for performance evaluation; or

(b) *in vitro* diagnostic 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.

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

(6) 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.

(7) 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 and 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.

(8) In England, Wales or Northern Ireland, for the purposes of the rights of appeal under section 15(5) and 16(5) of the 1987 Act, an order or decision not to make an order—

(a) under paragraph 7(a) is an order or decision not to make an order under section 15 of the 1987 Act;

(b) under paragraph 7(b) is an order or decision not to make an order under section 16 of the 1987 Act,

and a decision, in Scotland, not to make an order under paragraph 7(b) may, within 21 days of the decision, be appealed to the High Court by Bill of Suspension on the ground of an alleged miscarriage of justice, and the appeal shall be treated in the same way as an appeal under section 17(8) of the 1987 Act.

Transitional provisions

20.—(1) These Regulations shall not apply before 7th December 2003 in respect of a device placed on the market which is—

(a) a relevant 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.

(2) These Regulations shall not apply before 7th December 2005 in respect of a device put into service which is—

(a) a relevant 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.

Notification of decisions etc.

21.—(1) Any decision taken by a UK notified body, the Secretary of State or any other enforcement authority pursuant to these Regulations to refuse or restrict the placing on the

market or making available of a relevant device, or to withdraw a relevant device from the market, shall be notified to the person proposing to or responsible for placing the device on the market or putting the device into service without delay, 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 he 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.

Amendments to the 1994 Regulations

22. The amendments to the 1994 Regulations set out in Schedule 1 to these Regulations shall have effect.

Amendments to the 1995 Regulations

23. The amendments to the 1995 Regulations set out in Schedule 2 to these Regulations shall have effect.

Hunt
Parliamentary Under Secretary of State,
Department of Health

6th May 2000

We consent,

Clive Betts
Bob Ainsworth
Two of the Lords Commissioners of Her
Majesty's Treasury

11th May 2000

SCHEDULE 1

Regulation 22

AMENDMENTS TO THE 1994 REGULATIONS

1. In regulation 2(1) of the 1994 Regulations (interpretation)—

(a) for the definition of "authorised representative" there shall be substituted the following definition—

""authorised representative" means a person established within the Community 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;";

(b) after the definition of "intended purpose" there shall be inserted the following definition—

""*in vitro* diagnostic medical device" has the same meaning as in the *In Vitro* Diagnostic Medical Regulations 2000;";

(c) for the definition of "putting into service" there shall be substituted the following definition—

""putting into service" means, in relation to a device, the first making available of the device in the Community to a final user;"; and

(d) the definition of "used for *in vitro* diagnosis" is omitted.

2. In regulation 3(2) of the 1994 Regulations (application of the Regulations), for sub-paragraph (a) there shall be substituted the following sub-paragraph—

"(a) *in vitro* diagnostic medical devices;".

3. After regulation 12 of the 1994 Regulations (general provisions relating to conformity assessment procedures) there shall be inserted the following regulation—

"**CE marking of a product which is not a device**

12A.—(1) No person shall—

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

(b) place on the market a product which has affixed to it the CE marking for a device if that product is not a device.

(2) No person shall provide information comprising a CE marking for a relevant device on—

(a) a product;

(b) the instructions for use for a product; or

(c) the sales packaging for a product,

if the product is not a device.

(3) No person shall—

(a) supply, offer to supply, or agree to supply a product which has affixed to it a CE marking for a device if—

(i) that supply, offer to supply or agreement to supply a product is also a placing on the market of that product, and

(ii) that product is not a device;

(b) expose or possess for supply a product which has affixed to it a CE marking for a device if—

(i) that exposure for supply or possession for supply of a product is also a placing on the market of that product, and

(ii) that product is not a device.".

4. In regulation 14 of the 1994 Regulations (registration of persons placing devices on the market)—

(a) after sub-paragraph (b) of paragraph (1) there shall be inserted the following—

"; and

(c) supply the Secretary of State, if the device is a Class IIb or III device and if the Secretary of State so requests, 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."; and

(b) after sub-paragraph (b) of paragraph (3) there shall be added the following—

"; 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.".

5. In regulation 16 of the 1994 Regulations (clinical investigations)—

(a) in paragraph (1)(a), before the words "the statement required" there shall be inserted the words "subject to paragraph (1A),";

(b) after paragraph (1), there shall be inserted the following paragraph—

"(1A) 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."; and

(c) for paragraph (3) there shall be substituted the following paragraphs—

"(3) The Secretary of State may, in respect of notice in writing given by a manufacturer or his authorised representative under paragraph (1), give written notice to the manufacturer or his authorised representative that devices may be made available for the purposes of the intended investigation—

(a) at any time after the giving of notice under paragraph (1); or

(b) if the ethics committee opinion required under Section 2.2 of Annex VIII is not available, at any time after a favourable opinion in respect of the investigational plan for the intended investigation is delivered by the committee,

but that written notice may at any time be withdrawn by the Secretary of State.

(3A) Where a written notice under paragraph (3) has been withdrawn by the Secretary of State, devices may not be made available for the programme of clinical investigation to which that notice relates unless the Secretary of State issues a further written notice under that paragraph stating that devices may again be made available for the purposes of that investigation.".

6. In regulation 17 of the 1994 Regulations (notified bodies), after paragraph (7) there shall be inserted the following paragraphs—

"(8) Notified bodies shall 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 they shall also make available to them, on request, any or all additional relevant information.

(9) Where, as respects a device, a notified body finds—

(a) that applicable requirements of the Directive have not been met or are no longer met; or

(b) a certificate 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 19 or 19A, the notified body shall inform the Secretary of State thereof.

(10) The Secretary of State may request that a notified body supply to him any or all relevant information and documents, including budgetary documents, necessary to enable him to verify that the body meets the criteria set out in Annex XI, and the body shall supply to him the relevant information and documents so requested.".

7. For paragraph (1) of regulation 18 of the 1994 Regulations (prohibition on supply etc.) there shall be substituted the following paragraph—

"(1) Subject to paragraph (6), the supply, offer to supply, agreement to supply, exposure for supply or possession for supply of a device—

(a) which constitutes a placing on the market or putting into service of the device; or

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

if the device does not comply with the relevant essential requirements, is prohibited.".

8.—(1) In paragraph (3) of regulation 19 of the 1994 Regulations (enforcement etc.), after the words "and accordingly" there shall be added the words "but subject to paragraph (3A),".

(2) After paragraph (3) of regulation 19 of the 1994 Regulations there shall be inserted the following paragraph—

"(3A) The powers of an enforcement authority to serve restriction notices under regulation 19A are only exercisable by the Secretary of State.".

(3) For paragraphs (6) and (7) of regulation 19 of the 1994 Regulations there shall be substituted the following paragraphs—

"(6) In paragraph (5), "non-conforming devices" means devices which, whether or not the Secretary of State considers them unsafe, are devices with or which require a CE marking which he considers to be devices—

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

(b) to which a CE marking has or should have been applied following the EC declaration of conformity assessment procedure set out in the Directive, and—

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

(ii) they do not conform to the design or type described in any relevant EC design-examination or EC type-examination certificate.

(7) Except in the case of a device which in the opinion of an enforcement authority is likely to compromise the health or safety of any person, where an enforcement authority has reasonable grounds for suspecting that a device 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;

(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 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.".

9. After regulation 19 of the 1994 Regulations there shall be inserted the following regulation—

"**Restriction notices**

19A.—(1) Where an enforcement authority is of the opinion that it is necessary to restrict the availability of a particular device, or of devices 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) The enforcement authority responsible for serving a restriction notice may, in appropriate circumstances, withdraw the notice.

(3) 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.

(4) 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 and 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.

(5) In England, Wales or Northern Ireland, for the purposes of the rights of appeal under section 15(5) and 16(5) of the 1987 Act, an order or decision not to make an order—

(a) under paragraph 4(a) is an order or decision not to make an order under section 15 of the 1987 Act;

(b) under paragraph 4(b) is an order or decision not to make an order under section 16 of the 1987 Act,

and a decision, in Scotland, not to make an order under paragraph 4(b) may, within 21 days of the decision, be appealed to the High Court by Bill of Suspension on the ground of an alleged miscarriage of justice, and the appeal shall be treated in the same way as an appeal under section 17(8) of the 1987 Act.".

10. In paragraph (1) of regulation 22 of the 1994 Regulations (transitional provisions), after sub-paragraph (b) there shall be added the following—

"; or

(c) shall prohibit the putting into service before 30th June 2001 of a device which—

(i) was placed on the market on or before 31st December 1994, and

(ii) satisfies the requirements of the laws of that part of the United Kingdom in which it is put into service as in force on 31st December 1994.".

11. In paragraph (1) of regulation 23 of the 1994 Regulations (notification of decisions etc.)—

(a) after the words "in the refusal" there shall be inserted the words "or withdrawal of approval"; and

(b) after sub-paragraph (b) there shall be inserted the following—

"; and

(c) a statement, 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.".

SCHEDULE 2

Regulation 23

AMENDMENTS TO THE 1995 REGULATIONS

1. In regulation 2 of the 1995 Regulations (interpretation)—

(a) after the definition of "the 1994 Regulations" there shall be inserted the following definitions—

""the 1998 Directive" means Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices;

"the 2000 Regulations" means the *In Vitro* Diagnostic Medical Devices Regulations 2000;"; and

(b) after the definition of "half day" there shall be inserted the following definition—

""*in vitro* diagnostic medical device" has the same meaning as in the 2000 Regulations;".

2. After regulation 6 of the 1995 Regulations (withdrawals) there shall be inserted the following regulations—

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

7. Any person required to supply the Secretary of State with any information under regulation 14 of the 1994 Regulations shall, in respect of the processing of that information with regard to the possible registration of devices by the Secretary of State or possible changes to 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.

(2) Any person required to supply the Secretary of State with any information under regulation 14 of the 2000 Regulations shall, in respect of the processing of that information with regard to the possible registration of *in vitro* diagnostic medical devices by the Secretary of State or possible changes to 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 of UK notified bodies under regulation 15 of the 2000 Regulations

8.—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 15(1) of the 2000 Regulations 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;

(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 15(4) of the 2000 Regulations 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 15(7) of the 2000 Regulations 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 IX of the 1998 Directive are met, the body shall pay to the Secretary of State—

(a) in respect of an initial inspection pursuant to regulation 15(7)(a) of those Regulations, a fee of £3,200, plus—

(i) an amount for time spent by a member of staff out of the office while undertaking a site visit (to include time spent travelling) 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 of £51.39 per hour for time spent travelling,

(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 15(7)(a) of those Regulations, a fee of £2,600, plus—

(i) an amount for time spent by a member of staff out of the office while undertaking a site visit (to include time spent travelling) 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 of £51.39 per hour for time spent travelling,

(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 15(7)(b) of those Regulations, a fee of £2,600, plus—

(i) an amount for time spent by a member of staff out of the office while undertaking a site visit (to include time spent travelling) 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 of £51.39 per hour for time spent travelling,

(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—

(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, 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.

Unpaid fees

9. All unpaid sums due by way of, or on account of, any fees payable under these Regulations are recoverable as debts due to the Crown.

Waiver, reductions and refunds

10. The Secretary of State may—

(a) waive payment of any fee or reduce any fee or part of a fee otherwise payable under these Regulations;

(b) refund the whole or part of any fee paid pursuant to these Regulations.".

3. In the Table set out in the Schedule to the 1995 Regulations**(a)**, in the entries in Column 3—

(a) for the words "the rate of", at each place where they occur, there shall be substituted the words "a rate, for the time spent on site, of"; and

(b) after the words "any one date," at each place where they occur, there shall be added the words "and at a rate of £51.39 per hour for time spent travelling,".

(a) Amended by regulation 2 of S.I. 1997/694.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices ("the Directive").

Regulation 2 is an interpretation provision. Regulation 3 sets out the scope of the Regulations, and indicates which *in vitro* diagnostic medical devices are covered by the Regulations ("relevant devices"). Regulation 4 provides that relevant devices placed on the market, put in to service or (in certain circumstances) supplied must comply with the relevant essential requirements, as defined by reference to the essential requirements specified in Annex I of the Directive. Regulation 4 also sets out the factors to be taken into consideration when deciding whether a relevant device meets the essential requirements.

Regulation 5 requires relevant devices, their instructions for use and their sales packaging to bear a CE marking which meets the requirements of the Directive. Regulation 6 deals with the CE marking of relevant devices that come within the scope of more than one Directive, and regulation 7 contains prohibitions relating to relevant devices which are not ready for use.

Regulation 8 specifies exemptions from the requirements of regulations 4, 5 and 7, including exemptions in the interests of the protection of health. Regulation 9 sets out the procedures which manufacturers must follow for affixing the CE marking to relevant devices, and regulation 10 contains supplemental provisions relating to those procedures, including a number of additional requirements on manufacturers or their authorised representatives.

Regulation 11 creates prohibitions relating to the affixing of a CE marking for a relevant device to a product which is not a relevant device. Regulation 12 specifies, by reference to Annex VIII of the Directive, the rules in respect of making available devices for performance evaluation.

Regulations 13 and 14 relate to the registration of manufacturers, or their authorised representatives, of relevant devices and devices for performance evaluation, and the information they need to supply to the Secretary of State for registration purposes.

Regulation 15 deals with the designation of United Kingdom notified bodies and the circumstances in which such designations may be varied and withdrawn. Regulation 16 specifies the functions of such bodies. Regulation 17 makes provision for the fees chargeable by the notified bodies for work done in connection with the conformity assessment procedures set out in the Annexes to the Directive.

Regulation 18 specifies the responsibilities for enforcement in relation to the Regulations, and it provides that the Regulations are to be regarded for the purposes of enforcement as safety regulations as defined in the Consumer Protection Act 1987, although they are made partly in exercise of other powers. It also designates the Secretary of State as responsible for certain public health monitoring activities.

Regulation 19 contains a notice procedure for requiring compliance where there is a failure to comply with the requirements of the Regulations, and a further notice procedure for applying restrictions to the availability of devices where this is necessary to ensure the protection of health or safety.

Regulation 20 contains transitional provisions, and regulation 21 contains procedural requirements in relation to the notification of decisions by the Secretary of State, other enforcement authorities and the United Kingdom notified bodies.

Regulation 22 gives effect to Schedule 1 which contains amendments to the Medical Devices Regulations 1994 which are consequential upon amendments to Council Directive 93/42/EEC concerning medical devices**(a)** that were included in the Directive. The changes to Council Directive 93/42/EEC were essentially to align the requirements of the two Directives. Some additional changes have also been made to the 1994 Regulations to align the implementation approach adopted in those Regulations with the approach adopted in these Regulations, and there

(a) O.J. No. L169, 12.7.1993, p. 1.

are also changes to the system set out in the 1994 Regulations for obtaining the approval of ethics committees and the Secretary of State for proposed clinical investigations.

Regulation 23 gives effect to Schedule 2 which contains amendments to the Medical Devices Fees Regulations 1995 arising out of both the new scheme for *in vitro* diagnostic medical devices and the scheme in the Medical Devices Regulations 1994. There are new fees in connection with the registration scheme for relevant devices and devices for performance evaluation, as well as a new fee in connection with the registration scheme for certain medical devices. Notified bodies are also required to pay fees in relation to their designation scheme, and for certain inspections by the Secretary of State. The amendments also include some new enforcement provisions for the 1995 Regulations.

A Regulatory Impact Assessment in relation to these Regulations has 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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STATUTORY INSTRUMENTS

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