STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

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.

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 [M1], as amended [M2];

"Directive 93/42" means Council Directive 93/42/EEC of 14th June 1993 concerning medical devices [M3], as amended [M4];

"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 [M5];

"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 [M6];

"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 [M7], as adjusted by the Protocol signed at Brussels on 17th March 1993 [M8] ("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 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 [M9], 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

(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.

Marginal Citations

M1 OJ No. L. 189, 20.7.1990, p.17.

M2 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).

M3 OJ No. L 169, 12.7.1993, p.1.

M4 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).

M5 OJ No. L 331, 7.12.1998, p.1.

M6 OJ No. L 311, 28.11.2001, p.67.

M7 OJ No. L 1, 3.1.1994, p.3.

M8 OJ No. L 1, 3.1.1994, p.572.

M9 OJ No. L 204, 21.7.1998, p.37; amended by Directive 98/48/EC (OJ No. L 217, 5.8.1998, p.18).

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[M10], as amended [M11]; 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 [M12], as amended [M13].

Marginal Citations

M10 OJ No. L 262, 27.9.1976, p.169.

M11 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).

M12 OJ No. L 399, 30.12.1989, p.18.

M13 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).

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 [M14].

(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.

(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.

Marginal Citations

M14 S.I. 1993/2360.

Status:
Point in time view as at 13/06/2002.

Changes to legislation:
The Medical Devices Regulations 2002, PART I is up to date with all changes known to be in force on or before 26 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.