STATUTORY INSTRUMENTS

2008 No. 2936

CONSUMER PROTECTION

The Medical Devices (Amendment) Regulations 2008

Made - - - -	*12th November 2008*
Laid before Parliament	*19th November 2008*
Coming into force - -	*21st March 2010*

The Secretary of State makes the following Regulations, in exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972(**a**) and section 11 of the Consumer Protection Act 1987(**b**).

He is designated for the purpose of section 2(2) of the European Communities Act 1974 in relation to measures relating to medical devices(**c**).

In accordance with section 11(5) of the Consumer Protection Act 1984, he has consulted such organisations as appeared to him to be representative of interests substantially affected by these Regulations, such other persons as he considered appropriate and the Health and Safety Executive.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medical Devices (Amendment) Regulations 2008 and shall come into force on 21st March 2010.

(2) In these Regulations, "the principal Regulations" mean the Medical Devices Regulations 2002(**d**).

Amendment of regulation 2 of the principal Regulations

2. In regulation 2 of the principal Regulations (interpretation), in paragraph (1)—

(a) in the definition of "animal", after "animal" insert—

"for the purpose of regulations 13,17, 19A and 47";

(b) at the end of the definition of "authorised representative" insert—

"with regard to the latter's obligation under Directive 90/385, Directive 93/42 and Directive 98/79";

(c) after the definition of "the Community" insert—

(**a**) 1972 c.68; section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 c.51, section 27(1)(a).
(**b**) 1987 c.43; section 11 was amended by S.I. 2005/1803 and 2008/960; there are other amendments but none are relevant.
(**c**) The Secretary of State was designated in relation to measures relating to active implantable medical devices by SI. 1991/2289 and in relation to measures relating to medical devices other than active implantable medical devices in S.I. 1993/2661.
(**d**) S.I. 2002/618; as amended by S.I. 2003/1697 and S.I 2007/803.

""clinical data" means the safety or performance information that is generated from the use of a device, derived from—

(a) clinical investigations of the device concerned; or

(b) clinical investigations or other studies reported in scientific literature of a similar device for which equivalence to the device in question can be demonstrated; or

(c) published or unpublished reports on other clinical experiences of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;";

(d) after the definition of "Directive 2005/50", insert—

""Directive 2007/47" means Directive 2007/47/EC of the European Parliament and of the Council amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market(**a**);

"Directive 2006/42/EC" means Directive 2006/42/EC of the European Parliament and of the Council on machinery(**b**);";

(e) after the definition of "harmonised standard" insert—

""hazard" means a potential source of injury or damage to health;";

(f) for the definition of "intended for clinical investigation" substitute—

""intended for clinical investigation" means—

(a) intended for use by a registered medical practitioner when conducting investigations of that device in an adequate human clinical environment; or

(b) intended for use by any other person in a Member State who, by virtue of their professional qualification, is authorised to carry out investigations of that device in an adequate human clinical environment;";

(g) after the definition of "in vitro diagnostic medical device" insert—

""machinery" has the meaning given to it by Article 2(a) of Directive 2006/42;";

(h) in the definition of "medical device" for "an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application," substitute "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application,"; and

(i) omit the definition of "medical specialist".

Amendment of regulation 3 of the principal Regulations

3. In regulation 3 of the principal Regulations (scope of these Regulations)—

(a) in paragraph (d), omit "active implantable medical devices";

(b) in paragraph (d), after "such devices" insert "save where medicinal products are incorporated as ancillary to the device";

(c) in paragraph (e)(ii) omit "an active implantable medical device or"; and

(d) omit paragraph (g).

(**a**) OJ No. L247, 21.9.2007, p.21.
(**b**) OJ No. L157, 9.6.2006, p.24.

Amendment of regulation 5 of the principal Regulations

4. In regulation 5 of the principal Regulations (interpretation of Part II), in paragraph (1), in the definition of "custom-made device" for "duly qualified medical practitioner or professional user" substitute "registered medical practitioner, or other person authorised to write such a prescription by virtue of his professional qualification,".

Amendment of regulation 8 of the principal Regulations

5. In regulation 8 of the principal Regulations (essential requirements for general medical devices), after paragraph (2) add—

"(3) Where a hazard exists, devices which are also machinery shall also meet the essential health and safety requirements set out in Annex I to Directive 2006/42 to the extent to which those essential health and safety requirements are more specific than the essential requirements to Directive 93/42.".

Amendment of regulation 9 of the principal Regulations

6. In regulation 9 of the principal Regulations (determining compliance of general medical devices with relevant essential requirements)—

(a) after paragraph (5), insert—

"(5A) When a custom-made device is supplied to a patient, the healthcare professional who writes the prescription for the custom-made device shall, in relation to each patient that they supply with such a device—

(a) ensure that the patient is aware that they may request the statement containing the information required by Sections 1 and 2 of Annex VIII; and

(b) ensure that the statement containing the information required by Sections 1 and 2 of Annex VIII is made available to the patient on request."; and

(b) after sub-paragraph (8) insert—

"(9) Where a device is intended by the manufacturer to be used in conjunction with both the provisions in Council Directive 89/686/EEC on the approximation or the laws of the Member States relating to personal protective equipment(**a**) and Directive 93/42, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled.".

Amendment of regulation 14 of the principal Regulations

7. In regulation 14 of the principal Regulations (procedures for systems and procedure packs, and for devices to be sterilised before use), in paragraph (4)—

(a) for sub-paragraph (a), substitute—

"(a) follow the procedures referred to in either Annex II or IV that relate to obtaining sterility; and"; and

(b) after paragraph (4) insert—

"(4A) The application of Annex II or IV and the intervention of the notified body are limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged.".

Amendment of regulation 15 of the principal Regulations

8. In regulation 15 of the principal Regulations (procedure for custom-made general medical devices)—

(**a**) OJ No. L 399, 30.12.1989, p.18; as last amended by Regulation (EC) No. 1882/2003 (OJ No. L 284, 31.10.2003, p.1).

(1) at the end of paragraph (c) omit "and"; and

(2) after paragraph (d) insert—

";and

(e) ensures that the statement is passed on with the custom-made device so that it may be made available to the patient on request.".

Amendment of regulation 16 of the principal Regulations

9. In regulation 16 of the principal Regulations (procedures for general medical devices for clinical investigations) —

(a) in paragraph (1)(a)—

"for "Sections 1 and 2" substitute "Sections 1 and 2.2"; and

(b) after paragraph (10) add—

"(11) The manufacturer, or their single authorised representative, shall—

(a) notify the Secretary of State of the end of the clinical investigation; and

(b) provide justification where premature termination has resulted.".

Amendment of regulation 18 of the principal Regulations

10. In regulation 18 of the principal Regulations (UK notified bodies and conformity assessment procedures for general medical device), in paragraph (2), for "Annex II or III" substitute "Annex II, III, V or VI,".

Amendment of regulation 19 of the principal Regulations

11. In regulation 19 of the principal Regulations (registration of persons placing general medical devices on the market)—

(a) in paragraph (3), in sub-paragraph (c), for "the manufacturer's" substitute "the manufacturer's single authorised representative"; and

(b) in paragraph (5), for "Class IIb or III" (in each place that it occurs), substitute "Class IIa, IIb or III".

Amendment of regulation 21 of the principal Regulations

12. In regulation 21 of the principal Regulations (scope of Part III)—

(a) the existing paragraph shall be numbered (1); and

(b) after paragraph 1 add—

"(2) Where a hazard exists, devices which are also machinery shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I to Directive 90/385.

(3) Where an active implantable medical device is intended to administer a medicinal product, that device shall be governed by Directive 90/385 without prejudice to the provisions of Directive 2001/83/EC.".

Amendment of regulation 29 of the principal Regulations

13. In regulation 29 of the principal Regulations (procedures for active implantable medical devices for clinical investigations), after paragraph (9) add—

"(10) The manufacturer, or their single authorised representative, shall—

(a) notify the Secretary of State of the end of the clinical investigation; and

(b) provide justification where premature termination has resulted.".

Amendment of regulation 30 of the principal Regulations

14. In regulation 30 of the principal Regulations (manufacturers and conformity assessment procedures for active implantable medical devices), after paragraph (2), add—

"(3) Except as provided in paragraphs (4) and (5), the manufacturer of a relevant device, who under their own name places devices on the market, in accordance with the procedure referred to in Article 9(2) of Directive 90/385, shall provide the Secretary of State with—

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

(b) a description of the devices concerned; and

(c) details of the label and instructions for use that accompany each device.

(4) Where the manufacturer of a relevant device places a device on the market under their own name, but does not have a registered place of business in a Member State, the manufacturer shall—

(a) designate a single authorised representative; and

(b) ensure that the authorised representative has a registered place of business in a Member State.

(5) The authorised representative referred to in paragraph (4) shall provide the competent authority of the Member State in which they have their registered place of business with the information referred to in paragraph (3) above.".

Amendment of regulation 31 of the principal Regulations

15. In regulation 31 of the principal Regulations (UK notified bodies and conformity assessment procedures for active implantable medical devices), in paragraph (2), for "Annex 2 or 3" substitute "Annex 2, 3 or 5".

Amendment of regulation 47 of the principal Regulations

16. In regulation 47 of the principal Regulations (general matters relating to UK notified bodies), in paragraphs (4) and (5), omit the words "other than active implantable medical devices".

Amendment of regulation 60 of the principal Regulations

17. In regulation 60 of the principal Regulations (designation etc of authorised representatives)—

(a) in paragraphs (1), (2) and (3) replace the words "an authorised representative", in each place that they occur, with "a single authorised representative"; and

(b) in paragraph (4) replace "evidence that he is an authorised representative of the manufacturer" with "evidence that he is the single authorised representative of the manufacturer".

Amendment of regulation 63 of the principal Regulations

18. In regulation 63 of the principal Regulations (restriction notices)—

(a) in paragraph (1) omit "subject to paragraph (2),"; and

(b) omit paragraph (2).

Signed by authority of the Secretary of State for Health.

Dawn Primarolo
Minister of State,
Department of Health

12th November 2008

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medical Devices Regulations 2002 ("the principal Regulations"), to implement Directive 2007/47/EC of the European Parliament and of the Council(**a**).

The principal Regulations contain the legislative measures necessary for the implementation of the European Community scheme for regulating the placing on the market and putting into service of medical devices, including Council Directive 90/385/EEC concerning active implantable medical devices(**b**) and Council Directive 93/42/EEC concerning medical devices(**c**), as amended(**d**), which are amended by Directive 2007/47/EC.

Regulation 2 amends the principal Regulations with regard to the definitions of a medical device, a custom made device, intended purpose of a device, authorised representatives and clinical data.

Regulation 3 amends regulation 3 of the principal Regulations so as to provide that the Regulations apply to medical devices if they incorporate products made up of tissues or cells of human origin as an ancillary product. Regulation 3 also lists the products exempt from the provisions of Directive 90/385/EC to bring this in line with those set out in Directive 93/42/EC.

Regulation 4 amends regulation 5 of the principal Regulations to include reference to a duly qualified healthcare practitioner writing prescriptions for custom-made devices for the sole use of particular patients.

Regulations 5 and 12 amend regulation 6 and 21 of the principal Regulations to include a new requirement to apply the relevant health and safety requirements of Directive 2006/42/EC of the European Parliament and of the Council on machinery(**e**) for medical devices and active implantable devices that fall within the definition of a machine.

Regulation 6 amends regulation 9 of the principal Regulations making provisions concerning the supply of information to patients. Regulation 6 also sets out the application of protective personal equipment requirements under Council Directive 89/686/EEC(**f**) when a medical device has this dual purpose.

Regulation 7 amends regulation 14 of the principal Regulations, to specify which Annexes contain the relevant sterility procedures for this regulation.

Regulation 8 amends regulation 15 of the principal Regulations to ensure that the statement required for custom made devices is passed on to allow a patient access to it.

Regulations 9(a), 10 and 11 amend regulations 16, 18 and 19 of the principal Regulations respectively, in changing the conformity assessment and notification procedure. Regulations 9(b) and 13 amend regulation 29 of the principal Regulations to extend the new notification provisions

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(**a**) OJ No. L247, 21/9.2007, p.21.
(**b**) Council Directive 90/385/EEC has been amended by Directive 93/42/EEC (OJ No. L169, 12.7.1993, p.1), Directive 93/68/EEC (OJ No. L220, 30.8.93, p.1) and Regulation (EC) No. 1882/2003 (OJ No. L284, 31.10.2003, p.1).
(**c**) Council Directive 93/42/EEC has been amended by Directive 98/79/EC (OJ No. L331, 7.12.98, p.1), Directive 2000/70/EC (OJ No. L313, 13.12.2000, p.22), Directive 2001/104/EC (OJ No. L6, 10.1.2002), p.50) and Regulation (EC) No. 1882/2003 (OJ No. L284, 31.10.2003, p.1).
(**d**) Directive 2007/47/EC.
(**e**) OJ No. L157, 9.6.2006, p.24.
(**f**) Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment (OJ No. L399, 30.12.1989, p.18), as last amended by Regulation (EC) No. 1882/2003 (OJ No. L284, 31.10.2003, p.1).

now required for the end of a clinical investigation and justification where there has been early termination.

Regulation 14 amends regulation 30 of the principal Regulations to require that addresses of manufacturers be notified to the Secretary of State, along with details of their devices and labels, and for those who do not have a registered place of business in a Member State, designating a single authorised representative who must have a registered place of business within a Member State.

Regulations 15 and 16 amend regulation 31 of the principal Regulations to extend the application of Annex 5 as a relevant procedure within this regulation and to bring active implantable medical devices in line with general medical devices as far as conformity procedures are concerned. Regulation 18 amends regulation 63 of the principal Regulations to bring active implantable medical devices into line with other medical devices as far as restriction notices are concerned.

A full impact assessment of the effect that this instrument will have on the costs of business, and a Transposition Note in relation to the implementation of Directive 2007/470/EC, are available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

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