The Secretary of State makes the following Regulations, in exercise of the powers conferred on him by section 2(2) of, and paragraph 1A of Schedule 2 to, the European Communities Act 1972(1) and section 11 of the Consumer Protection Act 1987(2). He is designated for the purpose of section 2(2) of the European Communities Act 1972 in relation to medical devices(3).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for references to Annexes 1 to 7 to Directive 90/385/EEC, Annexes I to X to Directive 93/42/EEC, and Annex I to X to Directive 98/79/EC to be construed as a reference to those provisions as are amended from time to time.

In accordance with section 11(5) of the Consumer Protection Act 1987, 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 2012 and shall come into force on 1st July 2012.

(2) In these Regulations—

“the 2002 Regulations” means the Medical Devices Regulations 2002(4)

Amendment of the Medical Devices Regulations 2002

2. Regulation 2 (interpretation) of the Medical Devices Regulations 2002 is amended as follows:

(a) in paragraph (1),

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(1) 1972 c.68; section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 c.51, section 27(1)(a) and the European Union (Amendment) Act 2008 section 3(3) and Schedule Part 1.

(2) 1987 c.43; section 11 was amended by S.I.2005/1803 and 2008/960; there are other amendments but none are relevant.

(3) Designation in relation to active implantable medical devices is by S.I.1991/2289 and for other devices is by S.I.1993/2661.

(i) for the definition of “Directive 90/385”, substitute—


(ii) For the definition of “Directive 93/42”, substitute—


(iii) For the definition of “Directive 98/79”, substitute—


(b) after paragraph (1), insert—

“(1A) In these Regulations, any reference to Annexes 1 to 7 to Directive 90/385, Annexes I to X to Directive 93/42 or Annex I to X to Directive 98/79 is to be construed as a reference to those Annexes as amended from time to time.”.

Review

3.—(1) The Secretary of State must from time to time—

(a) carry out a review of the provisions within these Regulations;

(b) set out the conclusions of that review in a report; and

(c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how Directive 2007/47/EC(8) and Directive 2011/100/EU(9) are implemented in other member States.

(3) The report must in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by the provision of these Regulations that implement the Directives mentioned in paragraph (2);

(b) assess the extent to which those objectives are achieved;

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(4) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(5) Reports under this Regulation are afterwards to be published at intervals not exceeding five years.


Signed by authority of the Secretary of State for Health.

Earl Howe
Parliamentary Under-Secretary of State,
Department of Health

29th May 2012
EXPLANATORY NOTE

(This note is not part of the Regulations)


These Regulations amend the 2002 Regulations to allow references to Council Directives 90/385/EEC (OJ No.L.313, 13/12/2000, p.22) and 93/42/EEC, (OJ No.L.6, 10.1.2002, p.50) to include amendments by Directive 2007/47/EC. These Regulations also contain a review provision whereby the Secretary of State must carry out a review of these amending Regulations every five years.


These Regulations also amend references to Annexes 1 to 7 to Directive 90/385/EEC, Annexes I to X to Directive 93/42/EEC, and Annex I to X to Directive 98/79 (OJ No. L.331, 7.12.1998, p.1) by adding the words “as are amended from time to time”. The amendment is made in reliance on the powers in paragraph 1A of Schedule 2 to the European Communities Act 1972.

A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Medicines and Healthcare products Regulatory Agency, 151 Buckingham Palace Road, Victoria, London SW1W 9SZ and is published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk.