STATUTORY INSTRUMENTS

2012 No. 1426

CONSUMER PROTECTION

The Medical Devices (Amendment) Regulations 2012

Made - - - -	*29th May 2012*
Laid before Parliament	*11th June 2012*
Coming into force - -	*1st July 2012*

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),

(**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.
(**4**) S.I.2002/618; as amended by S.I.2003/1697, 2007/803 and 2008/2936.

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

""Directive 90/385" means Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of Member States relating to active implantable devices(**5**).".

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

""Directive 93/42" means Council Directive 93/42/EEC of 14 June 1993 concerning medical devices(**6**).".

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

""Directive 98/79" means Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices(**7**).".

(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.

(**5**) Directive 90/385/EEC as amended by Council Directive 93/43/EEC (OJ No.L.169, 12/7/1993, p.1), Council Directive 93/68/EEC (OJ No.L.220, 30.8.1993, p.1), Regulation (EC) No.1882/2003 (OJ No. L284, 31.10.2003, p.1) and Directive 2007/47/EC (OJ No. 1.247, 21.9.2007, p.21).

(**6**) Directive 93/42/EEC was 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), Directive 2001/104/EU (OJ No. L.6, 10.1.2002, p.50) and Directive 2007/47/EC (OJ No. L.247, 21.9.2007, p.21).

(**7**) Directive 98/79/EC was amended by Regulation (EC) No 1882/2003 (OJ No. L.284, 31.10.2003, p.1), Regulation (EC) No. 596/2009 (OJ No. L.188, 18.7.2009, p.14) and Directive 2011/100 (OJ No. L.341, 22.12.2011, p.50) and was corrected by Corrigendum (OJ No. L.22, 29.1.1999, p.75) and Corrigendum (OJ No. L.6, 10.1.2002, p.70).

(**8**) Directive 2007/47/EC of the European Parliament and of the Council (OL No.L.247, 21.9.2007, p.21-55).

(**9**) Commission Directive 2011/100/EU (OJ No.L.341, 22.12.2011, p.50).

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 Medical Devices Regulations 2002 (S.I.2002/618), as most recently amended by the Medical Devices (Amendment) Regulations 2008 (S.I.2008/375) ("the 2008 Regulations"). The 2008 Regulations implement Directive 2007/47/EC of the European Parliament and of the Council (OJ No.L.247, 21.09.2007, p.21).

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 implement Commission Directive 2011/100/EU (OJ No.L.341, 22.12.2011, p.50), which amends Council Directive 98/79/EC (OJ No. L.331, 7/12/1998, p.1). The effect of this is to add to List A of Annex II of Council Directive 98/79/EC, variant Creutzfeldt-Jakob disease (vCJD) assays for blood screening, diagnosis and confirmation. This will ensure that notified bodies must verify conformity with the essential requirements of Annex I of that Directive.

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