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STATUTORY INSTRUMENTS

2013 No. 2327

CONSUMER PROTECTION

The Medical Devices (Amendment) Regulations 2013

Made - - - -	*12th September 2013*
Laid before Parliament	*19th September 2013*
Coming into force - -	*21st October 2013*

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**a**), section 56(1) and (2) of the Finance Act 1973(**b**) and section 11 of the Consumer Protection Act 1987(**c**).

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to medical devices(**d**).

The Secretary of State has obtained the consent of the Treasury in accordance with section 56(1) of the Finance Act 1973.

The Secretary of State has consulted such organisations that appear to him to be representative of the interests substantially affected by these Regulations, such other persons as he considers appropriate and the Health and Safety Executive in accordance with section 11(5) of the Consumer Protection Act 1987.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medical Devices (Amendment) Regulations 2013.

(2) These Regulations shall come into force on 21st October 2013.

(3) In these Regulations "the 2002 Regulations" means the Medical Devices Regulations 2002(**e**).

Amendment of regulation 2 of the 2002 Regulations

2.—(1) Regulation 2 of the 2002 Regulations (interpretation) is amended as follows.

(2) In paragraph (1) omit the following definitions—

(a) "animal";

(**a**) 1972 c.68; section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and section 3(3) of and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c. 7).
(**b**) 1973 c.51; section 56(1) was amended by S.I. 2011/1043.
(**c**) 1987 c.43; section 11 was amended by S.I. 2005/1803 and 2008/960.
(**d**) S.I. 1991/2289 for active implantable medical devices and S.I. 1993/2661 for all other devices.
(**e**) S.I. 2002/618; relevant amending instruments are S.I. 2003/1697, 2005/2759, 2008/2936, 2011/1043 and 2012/1426.

(b) "Directive 2003/32";

(c) "EEA State";

(d) "non-viable"; and

(e) "tissue".

(3) In paragraph (1) for the definition of "European Economic Area" substitute—

""European Economic Area" means the European Economic Area created by the EEA Agreement;".

(4) In paragraph (1) in the definition of "the Medical Devices Directives" for "read with Directive 2003/32" substitute "both read with Regulation (EU) No 207/2012 and Regulation (EU) No 722/2012".

(5) In paragraph (1) after the definition of "putting into service" insert the following definitions—

""Regulation (EU) No 207/2012" means Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices(**a**);

"Regulation (EU) No 722/2012" means Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin(**b**);".

(6) After paragraph (1A) insert the following paragraph—

"(1B) In these Regulations, any reference to Annex 1 to Directive 90/385 or to Annex I to Directive 93/42 is to that Annex read with Regulation (EU) No 207/2012.".

Amendment of regulation 8 of the 2002 Regulations

3. In regulation 8(1) and (2) of the 2002 Regulations (essential requirements for general medical devices) after "apply to it" insert "and the requirements set out in Regulation (EU) No 722/2012 (if applicable)".

Amendment of regulation 13 of the 2002 Regulations

4.—(1) Regulation 13 of the 2002 Regulations (procedures for affixing a CE marking to general medical devices) is amended as follows.

(2) In paragraph (4)—

(a) in sub-paragraph (b) omit "and";

(b) at the end of sub-paragraph (c) add "and"; and

(c) after sub-paragraph (c) add the following sub-paragraph—

"(d) fulfils the obligations imposed by Regulation (EU) No 722/2012 (if applicable)."

(3) Omit paragraphs (5) and (6).

Amendment of regulation 15 of the 2002 Regulations

5. In regulation 15(a) of the 2002 Regulations (procedures for custom-made general medical devices) after "Annex VIII" insert ", read with Regulation (EU) No 722/2012".

(**a**) OJ No L 72, 10.3.2012, p.28.
(**b**) OJ No L 212, 9.8.2012, p.3.

Amendment of regulation 16 of the 2002 Regulations

6. In regulation 16(1)(a) of the 2002 Regulations (procedures for general medical devices for clinical investigations) after "Annex VIII" insert ", read with Regulation (EU) No 722/2012".

Amendment of regulation 17 of the 2002 Regulations

7. Omit regulation 17(4) and (5) of the 2002 Regulations (manufacturers etc. and conformity assessment procedures for general medical devices).

Amendment of regulation 18 of the 2002 Regulations

8. In regulation 18(1)(b) of the 2002 Regulations (UK notified bodies and the conformity assessment procedures for general medical devices) for "EEA State" substitute "EEA State".

Omission of regulation 19A of the 2002 Regulations

9. Omit regulation 19A of the 2002 Regulations (additional requirements relating to use of animal tissue).

Amendment of regulation 22 of the 2002 Regulations

10. In regulation 22(1) and (2) of the 2002 Regulations (essential requirements for active implantable medical devices) after "apply to it" insert "and the requirements set out in Regulation (EU) No 722/2012 (if applicable)".

Amendment of regulation 27 of the 2002 Regulations

11. In regulation 27 of the 2002 Regulations (procedures for affixing a CE marking to active implantable medical devices)—

(a) in paragraph (b) omit "and";

(b) at the end of paragraph (c) add "and"; and

(c) after paragraph (c) add the following paragraph—

"(d) fulfils the obligations imposed by Regulation (EU) No 722/2012 (if applicable)."

Amendment of regulation 28 of the 2002 Regulations

12. In regulation 28(a) of the 2002 Regulations (procedures for custom-made active implantable medical devices) after "Annex 6" insert ", read with Regulation (EU) No 722/2012".

Amendment of regulation 29 of the 2002 Regulations

13. In regulation 29(1)(a) of the 2002 Regulations (procedures for general medical devices for clinical investigations) after "Annex 6" insert ", read with Regulation (EU) No 722/2012".

Amendment of regulation 45 of the 2002 Regulations

14.—(1) Regulation 45 of the 2002 Regulations (designation etc. of UK notified bodies) is amended as follows.

(2) In paragraph (2)(a) after "Annex 8 of that Directive" insert ", read with Regulation (EU) No 722/2012,".

(3) In paragraph (2)(b) for "article 4 of Directive 2003/32" substitute "Regulation (EU) No 722/2012".

(4) In paragraphs (5)(b), (7) and (8) for "read with article 4 of Directive 2003/32" substitute "both read with Regulation (EU) No 722/2012".

Amendment of regulation 47 of the 2002 Regulations

15. Omit regulation 47(9) and (10) of the 2002 Regulations (general matters relating to UK notified bodies).

Amendment of regulation 54 of the 2002 Regulations

16. In regulation 54(3) of the 2002 Regulations (fees payable in connection with the designation etc. of UK notified bodies) for "read with article 4 of Directive 2003/32" substitute "both read with Regulation (EU) No 722/2012".

Amendment of regulation 61 of the 2002 Regulations

17. In regulation 61(8)(a)(i) of the 2002 Regulations (enforcement etc.) after "requirement" insert "or a requirement of Regulation (EU) No 722/2012 (if applicable)".

Insertion of regulation 67 into the 2002 Regulations

18. After regulation 66 of the 2002 Regulations (revocations) insert the following regulation—

"Review

67. Before the end of 31st December 2019, the Secretary of State must—

(a) carry out a review of these Regulations;

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

(c) publish the report.".

Amendment of Schedule 1 to the 2002 Regulations

19. For paragraph 1 of Schedule 1 to the 2002 Regulations (association agreements) substitute—

"**1.** The Agreement establishing an Association between the European Economic Community and Turkey signed at Ankara on 12th September 1963.".

Amendment of Schedule 2 to the 2002 Regulations

20. In Schedule 2 to the 2002 Regulations (mutual recognition agreements) after paragraph 4 add the following paragraph—

"**5.** The agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment signed in Luxembourg on 21st June 1999.".

Part-revocation of the Medical Devices (Amendment) Regulations 2003

21. The following provisions of the Medical Devices (Amendment) Regulations 2003(**a**) are revoked—

(a) regulation 2(b), (c) insofar as it inserts a definition of "Directive 2003/32", (e) and (g);

(b) regulation 6;

(c) regulation 7;

(d) regulation 9;

(e) regulation 13;

(**a**) S.I. 2003/1697.

(f) regulation 14; and

(g) regulation 16.

Part-revocation of the Medical Devices (Amendment) Regulations 2012

22. Regulation 3 of the Medical Devices (Amendment) Regulations 2012(**a**) (review) is revoked.

Signed by authority of the Secretary of State for Health.

Earl Howe
Parliamentary Under-Secretary of State,
12th September 2013 Department of Health

We consent

Desmond Swayne
Mark Lancaster
12th September 2013 Two of the Lords Commissioners of Her Majesty's Treasury

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medical Devices Regulation 2002 (the 2002 Regulations) in order to implement Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices and Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin.

Regulation 2(4) to (6) ensures that the requirements directly imposed under Commission Regulation (EU) No 207/2012 on manufacturers who adopt electronic labelling of medical devices are enforceable in the UK.

Regulations 2(2), (4) and (5), 3 to 7, 9 to 17 and 21 ensure that the requirements directly imposed under Commission Regulation (EU) No 722/2012 on manufacturer of medical devices that utilise tissue of animal origin are enforceable in the UK; and remove national requirements which duplicate requirements directly applicable under the Commission Regulation.

Regulations 2(2) and (3), 8, 19 and 20 update the 2002 Regulations to take account of changes in the membership of the European Union.

Regulation 18 requires the Secretary of State to review the 2002 Regulations and publish a report by 31st December 2019.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, public or voluntary sectors is foreseen.

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(**a**) S.I. 2012/1426.

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