STATUTORY INSTRUMENTS

2003 No. 1697

CONSUMER PROTECTION

The Medical Devices (Amendment) Regulations 2003

Made - - - -	*4th July 2003*
Laid before Parliament	*11th July 2003*
Coming into force	
except for the purposes of regulations 3(b), 6, 7 and 9	*1st September 2003*
for the purposes of regulations 3(b), 6, 7 and 9	*1st April 2004*

The Secretary of State, being a Minister designated for the purposes of section 2(2) of the European Communities Act 1972(**1**) in relation to measures relating to medical devices(**2**), in exercise of the powers conferred by the said section 2(2), in exercise of the powers conferred by section 11 of the Consumer Protection Act 1987(**3**) and in exercise of all other powers enabling him in that behalf, after consultation in accordance with section 11(5) of the Consumer Protection Act 1987 with organisations appearing to him to be representative of interests substantially affected by these Regulations, with such other persons considered by him appropriate and with the Health and Safety Commission, hereby makes the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medical Devices (Amendment) Regulations 2003 and shall come into force—

(a) except for the purposes of regulations 3(b), 6, 7 and 9, on 1st September 2003; and

(b) for the purposes of regulations 3(b), 6, 7 and 9, on 1st April 2004.

(2) In these Regulations, the "principal Regulations" means the Medical Devices Regulations 2002(**4**).

(**1**) 1972 c. 68.
(**2**) The Secretary of State was designated in relation to measures relating to active implantable medical devices in S.I.1991/2289 and in relation to measures relating to medical devices other than active implantable medical devices in S.I. 1993/2661.
(**3**) 1987 c. 43.
(**4**) S.I. 2002/618.

Amendment of regulation 2 of the principal Regulations

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

(a) the words ", unless the context otherwise requires" are omitted;

(b) after the definition of "active implantable device", there is inserted the following definition—

""animal" means any animal from a bovine, ovine or caprine species, as well as deer, elk, mink and cats;";

(c) after the definition of "Directive 2001/83", there is inserted the following definitions—

""Directive 2003/12" means Commission Directive 2003/12(**5**) of 3rd February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC(**6**) concerning medical devices;

"Directive 2003/32" means Commission Directive 2003/32(**7**) of 23rd April 2003 on medical devices manufactured utilising tissues of animal origin;";

(d) in the definition of "the Medical Devices Directives", after "Directive 93/42" there is inserted ", read with Directive 2003/32";

(e) after the definition of "national standard", there is inserted the following definition—

""non-viable" means having no potential for metabolism or multiplication;";

(f) in the definition of "notified body", for "Part V of" there is substituted "Part V or"; and

(g) after the definition of "third country conformity assessment body", there is inserted the following definition—

""tissue" means an organisation of cells and/or extra-cellular constituents;".

Amendment of regulation 4 of the principal Regulations

3. In regulation 4 of the principal Regulations (transitional provisions)—

(a) after paragraph (4) there is inserted the following paragraph—

"(5) Regulation 13(4) shall not be applied before 1st March 2004 in respect of breast implants which—

(a) bore a CE marking before 1st September 2003; and

(b) satisfy the requirements in respect of relevant devices falling within Class IIb set out in regulation 13(3).";and

(b) after paragraph (5) there shall be added the following paragraph—

"(6) Regulation 19A shall not be applied before 1st October 2004 in respect of a device placed on the market before 1st April 2004.".

Amendment of regulation 5 of the principal Regulations

4. In regulation 5(1) and (2) of the principal Regulations (interpretation of Part II), the words ", unless the context otherwise requires" are omitted.

(**5**) OJNo. L 28, 4.2.2003, p.43.
(**6**) OJ No. L 169, 12.7.1993, p.1; 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).
(**7**) OJ No. L 105, 26.4.2003, p.18.

Amendment of regulation 7 of the principal Regulations

5. In regulation 7 of the principal Regulations (classification of general medical devices), after "Directive 93/42", at both places where this occurs, there is inserted ", read with Directive 2003/12".

Amendment of regulation 13 of the principal Regulations

6. In regulation 13 of the principal Regulations (procedures for affixing a CE marking to general medical devices), after paragraph (4) there is added the following paragraphs—

"(5) Notwithstanding that the requirement in paragraph (1) to (4) is satisfied, subject to paragraph (6), where a relevant device is manufactured utilising either animal tissue which is rendered non-viable or non-viable products derived from animal tissue its manufacturer or his authorised representative must—

(a) carry out the risk analysis and risk management procedures set out in the Annex to Directive 2003/32; and

(b) fulfil his obligations under those procedures

before the device may bear a CE marking.

(6) Paragraph (5) shall not apply to a relevant device which is not intended to come into contact with the human body or which is intended to come into contact with intact skin only.".

Amendment of regulation 17 of the principal Regulations

7. In regulation 17 of the principal Regulations (manufacturers etc. and conformity assessment procedures for general medical devices), after paragraph (3) there is added the following paragraphs—

"(4) Subject to paragraph (5), where a relevant device is manufactured utilising either animal tissue which is rendered non-viable or non-viable products derived from animal tissue, the manufacturer of that device or, where applicable, his authorised representative who is required to carry out, or carries out or has carried out the risk analysis and risk management procedures set out in the Annex to Directive 2003/32 shall observe the manufacturer's obligations set out in those procedures.

(5) Paragraph (4) shall not apply to a relevant device which is not intended to come into contact with the human body or which is intended to come into contact with intact skin only.".

Amendment of regulation 18 of the principal Regulations

8. In regulation 18 of the principal Regulations (UK notified bodies and the conformity assessment procedures for general medical devices), after paragraph (3) there is added the following paragraph—

"(4) Decisions taken by UK notified bodies before 1st September 2003 in accordance with Annex II in respect of breast implants may not be extended.".

New regulation 19A of the principal Regulations

9. In Part II of the principal Regulations (general medical devices), after regulation 19 (registration of persons placing general medical devices on the market) there is inserted the following regulation—

"**Additional requirements relating to use of animal tissues**

19A.—(1) Subject to paragraph (3), no person shall put into service or supply a relevant device (if that supply is also a placing on the market or if that supply is of a relevant device that has been placed on the market) if that device is manufactured utilising either animal tissue which is rendered non-viable or non-viable products derived from animal tissue unless—

(a) there is in respect of that device a risk analysis and risk management scheme which is in accordance with the requirements of Directive 2003/32; and

(b) the manufacturer of the device has fulfilled his obligations under the procedures within that scheme.

(2) If collagen, gelatine or tallow is of animal origin and has been used in the manufacture of a relevant device, then subject to paragraph (3), no person shall put into service or supply that device (if that supply is also a placing on the market or if that supply is of a device that has been placed on the market), unless that collagen, gelatine or tallow was fit for human consumption.

(3) Paragraphs (1) and (2) shall not apply to a relevant device which is not intended to come into contact with the human body or which is intended to come into contact with intact skin only.".

Amendment of regulation 20 of the principal Regulations

10. In regulation 20 of the principal Regulations (interpretation of Part III)—

(a) in paragraphs (1) and (2) the words ", unless the context otherwise requires" are omitted;

(b) in paragraph (2), the words "article or", at both places where they occur, are omitted.

Amendment of regulation 32 of the principal Regulations

11. In regulation 32(1) and (2) of the principal Regulations (interpretation of Part IV), the words ", unless the context otherwise requires" are omitted.

New regulation 44A of the principal Regulations

12. In Part V of the principal Regulations (notified bodies, conformity assessment bodies and marking of products), before regulation 45 (designation etc. of UK notified bodies) there is inserted the following regulation—

"**Interpretation of Part V**

44A. In this Part, "medical device" means a device that is a "relevant device" for the purposes of Part II, III or IV.".

Amendment of regulation 45 of the principal Regulations

13. In regulation 45 of the principal Regulations (designation etc. of UK notified bodies)—

(a) in paragraph (2)(b), after "that Directive" there is inserted ", read with article 4 of Directive 2003/32,"; and

(b) in paragraphs (5)(b), (7) and (8), after "Directive 93/42" there is inserted ", read with article 4 of Directive 2003/32".

Amendment of regulation 47 of the principal Regulations

14. In regulation 47 of the principal Regulations (general matters relating to UK notified bodies), after paragraph (8) there is added the following paragraphs—

"(9) Subject to paragraph (10), a UK notified body that is designated to carry out the tasks referred to in article 5 of Directive 2003/32 shall, when performing conformity evaluation of a relevant device manufactured utilising either animal tissue which is rendered non-viable or non-viable products derived from animal tissue, evaluate the matters mentioned in article 5.2 of Directive 2003/32, and in so doing shall—

(a) take account of any relevant certificate of suitability that has been issued by the European Directorate for the Quality of Medicines in respect of either any animal tissues which are rendered non-viable or non-viable products derived from animal tissue which are utilised or intended to be utilised in that device; or

(b) if no relevant certificate of suitability is available—

(i) seek the opinion of the Secretary of State and through the Secretary of State the opinion of other Member States on the UK notified body's evaluation and conclusions on the risk analysis and risk management of the animal tissues or products derived from animal tissue utilised or intended to be utilised in that device, as established by the manufacturer or his authorised representative, and

(ii) where the UK notified body receives any comments from the Secretary of State and where applicable from other Member States that have commented within twelve weeks of those opinions being sought by the Secretary of State, give due consideration to any such comments,

and where the Secretary of State's opinion is sought pursuant to sub-paragraph (b)(i), the UK notified body shall supply him with the information and documents he needs or reasonably requests in order to formulate his opinion.

(10) Paragraph (9) shall not apply to a relevant device which is not intended to come into contact with the human body or which is intended to come into contact with intact skin only.".

Amendment of regulation 52 of the principal Regulations

15. In regulation 52(1) of the principal Regulations (interpretation of Part VI), the words ", unless the context otherwise requires" are omitted.

Amendment of regulation 54 of the principal Regulations

16. In paragraph (3) of regulation 54 of the principal Regulations (fees payable in connection with the designation etc. of UK notified bodies), after "Directive 93/42" there is inserted ", read with article 4 of Directive 2003/32".

Amendment of regulation 59 of the principal Regulations

17. In regulation 59 of the principal Regulations (interpretation of Part VII), the words ", unless the context otherwise requires" are omitted.

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under-Secretary of State,
4th July 2003 Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medical Devices Regulations 2002 ("the principal Regulations"), which 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. The amendments include amendments that are necessary for the implementation of Commission Directive 2003/12 of 3rd February 2003 on the reclassification of breast implants within the framework of Directive 93/42/EEC on medical devices ("Directive 2003/12") and Commission Directive 2003/32 of 23rd April 2003 on medical devices utilising tissues of animal origin ("Directive 2003/32").

Regulation 2 introduces new definitions into the principal Regulations, and amends another definition to take account of Directive 2003/32.

Regulation 5 requires breast implants to be reclassified as Class III devices, from Class IIb. Regulation 3(a) delays the effect of this reclassification by six months for products already on the market on 1st September 2003. Regulation 8 prevents notified bodies from extending earlier decisions on breast implants, taken on the basis that they were Class IIb devices, for longer than Directive 2003/12 allows.

Regulations 6, 7 and 9 set new conditions relating to the manufacture and supply of general medical devices manufactured utilising tissues of animal origin. Regulation 3(b) delays the application of these new requirements in relation to devices placed on the market before 1st April 2004.

Regulation 12 inserts a new definition for the purposes of Part V of the principal Regulations to ensure that the requirements relating to the incorrect marking of products cover all the products that may be incorrectly marked with a notified body number, conformity assessment body number or CE marking.

Regulation 13 amends the scheme for designating bodies as notified bodies to take account of the extension, by virtue of Directive 2003/32, of the tasks for which notified bodies may be designated, and regulation 16 makes a consequential amendment to the fees provisions. Regulation 14 includes new obligations on notified bodies when evaluating devices manufactured utilising tissues of animal origin.

Regulation 2(a) and (f)—and also regulations 4, 10, 11, 15 and 17—correct drafting errors in the principal Regulations.

Regulatory Impact Assessments in relation to these Regulations, and a Transposition Note in relation to the implementation of Directives 2003/12 and 2003/32, have been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medicines and Healthcare products Regulatory Agency, Hannibal House, Elephant and Castle, London SE1 6TQ.