STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART II

General Medical Devices

Interpretation of Part II

5.—(1) In this Part [F1]...—

"accessory" means an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by its manufacturer;

"custom-made device" means a relevant device that is—

(a) manufactured specifically in accordance with a written prescription of a duly qualified medical practitioner or a professional user which gives, under his responsibility, specific characteristics as to its design; and

(b) intended for the sole use of a particular patient,

but does not include a mass-produced product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user;

"relevant device" shall be construed in accordance with regulation 6;

"single-use combination product" means a product which comprises a medical device and medicinal product forming a single integral product which is intended exclusively for use in the given combination and which is not reusable; and

"system or procedure pack" has the same meaning as in article 12 of Directive 93/42.

(2) In this Part [F1]..., a reference to a numbered article or Annex is to the article or Annex of Directive 93/42 bearing that number.

Textual Amendments

F1 Words in reg. 5(1)(2) omitted (1.9.2003) by virtue of The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **4**

Scope of Part II

6. The requirements of this Part in respect of relevant devices apply in respect of medical devices (including stable derivatives devices), accessories to such devices, single-use combination products, and systems and procedure packs, other than—

(a) active implantable medical devices and accessories to such devices;

(b) *in vitro* diagnostic medical devices and accessories to such devices; and

(c) devices that come within the scope of Directive 93/42 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, and

(i) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it, and

(ii) the manufacturer chooses to follow the set of arrangements in the other Directive.

Classification of general medical devices

7.—(1) For the purposes of this Part and Part VI, devices are classified as belonging to Class I, IIa, IIb or III in accordance with the classification criteria set out in Annex IX of Directive 93/42 **[**F2, read with Directive 2003/12**][**F3and Directive 2005/50**]**.

(2) In the event of a dispute between a manufacturer and a notified body over the classification of a device, the matter shall be referred to the Secretary of State, who shall determine the classification of the device in accordance with the classification criteria set out in Annex IX of Directive 93/42**[**F2, read with Directive 2003/12**][**F3and Directive 2005/50**]**.

Textual Amendments

F2 Words in reg. 7 inserted (1.9.2003) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **5**

F3 Words in reg. 7 inserted (1.9.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(b), **5**

Essential requirements for general medical devices

8.—(1) Subject to regulation 12, no person shall place on the market or put into service a relevant device unless that device meets those essential requirements set out in Annex I which apply to it.

(2) Subject to regulation 12, no person shall supply a relevant device—

(a) if that supply is also a placing on the market or putting into service of that device; or

(b) in circumstances where that device has been placed on the market or put into service,

unless that device meets those essential requirements set out in Annex I which apply to it.

Determining compliance of general medical devices with relevant essential requirements

9.—(1) In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) Where confirmation of conformity with the essential requirements must be based on clinical data, such data must be established in accordance with the requirements set out in Annex X.

(3) In the case of a relevant device which is being or has been put into service—

(a) the essential requirements specified in Sections 8.7 and 13 of Annex I with regard to information on the packaging and on any label are complied with only if such information is in English (whether or not it is also in another language and whether or not the device is for professional use); and

(b) the essential requirements specified in Sections 11.4 and 13 of Annex I with regard to instructions for use are complied with only if—

(i) such instructions are in English or another Community language, and

(ii) if the instructions are not in English, any packaging, label or promotional literature carries a clear statement in English stating the language in which the instructions are given.

(4) A relevant device shall be treated as complying with an essential requirement if it conforms as respects that requirement to a relevant national standard, unless there are reasonable grounds for suspecting that it does not comply with that requirement.

(5) A custom-made device—

(a) in respect of which the conditions specified in Annex VIII are satisfied; and

(b) in the case of a Class IIa, Class IIb and Class III device, which is accompanied by the statement required by Section 1 of Annex VIII,

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

(6) Where, in accordance with Section 2.1 of Annex VIII, a manufacturer of a custom-made device, or his authorised representative, has indicated that specified essential requirements have not been fully met, and has given proper grounds as to why they have not been fully met, those specified essential requirements are no longer to be treated as relevant essential requirements for that device.

(7) A device intended for clinical investigation in respect of which—

(a) the conditions specified in Annex VIII are satisfied;

(b) notice has been given under regulation 16(1); and

(c) either—

(i) no notice has been given under regulation 16(4) within the period of 60 days there referred to, or

(ii) notice has been given under regulation 16(5),

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

(8) A single-use combination product shall be taken to comply with the relevant essential requirements if the medical device which forms part of that product only complies with the requirements set out in Annex I of Directive 93/42 that relate to safety and performance, unless the medicinal product which forms part of that product is liable to act on the human body with action ancillary to that of the medical device, in which case the single-use combination product must comply with all the relevant essential requirements which apply to it.

CE marking of general medical devices

10.—(1) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless, where practical and appropriate, that device or its sterile pack bears a CE marking which—

(a) meets the requirements set out in Annex XII;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(2) Subject to regulations 12 and 14, no person shall supply a relevant device unless, where practical and appropriate, that device or its sterile pack bears a CE marking which—

(a) meets the requirements set out in Annex XII;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless a CE marking, meeting the requirements set out in Annex XII, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for the device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(4) Subject to regulations 12 and 14, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless a CE marking, meeting the requirements set out in Annex XII, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for the device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(5) No person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

(a) a relevant device or its sterile pack;

(b) the instructions for use for a relevant device; or

(c) any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the CE marking or which reduces the visibility or the legibility of the CE marking.

CE marking of general medical devices that come within the scope of more than one Directive

11. Where a relevant device comes within the scope of Directive 93/42 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, no person shall affix a CE marking to the device unless the relevant requirements of the other Directive are also satisfied, except where—

(a) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it;

(b) the manufacturer chooses to follow the set of arrangements in Directive 93/42;

(c) the marking of the device indicates that the device only satisfies the set of arrangements chosen by the manufacturer; and

(d) the particulars of Directive 93/42, as published in the Official Journal of the European Communities, are given in the documents, notices or instructions accompanying the device.

Exemptions from regulations 8 and 10

12.—(1) A relevant device or a single use combination product being shown at a trade fair, exhibition, demonstration or similar gathering is not being placed on the market or put into service

if a visible sign clearly indicates that the device or product cannot be marketed or put into service until it complies with the requirements of Directive 93/42 or these Regulations.

(2) Regulation 10 shall not apply to a custom-made device or a device intended for clinical investigation.

(3) Regulation 10 shall not apply to a relevant device which is a system or procedure pack, unless—

(a) the system or procedure pack incorporates a medical device which does not bear a CE marking; or

(b) the chosen combination of medical devices is not compatible in view of their original intended use.

(4) Regulation 10 shall not apply to single-use combination products, unless the medicinal product which forms part of that product is liable to act on the human body with action ancillary to that of the medical device which forms part of that product.

(5) Regulations 8 and 10 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a CE marking, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

Procedures for affixing a CE marking to general medical devices

13.—(1) A relevant device falling within Class I may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by Annex VII;

(b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 93/42 which apply to it; and

(c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

(2) A relevant device falling within Class IIa may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex II, excluding Section 4 of that Annex, or

(ii) Annex VII, together with Annex IV, V or VI;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and

(c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

(3) A relevant device falling within Class IIb may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex II, excluding Section 4 of that Annex, or

(ii) Annex III, together with Annex IV, V or VI;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and

(c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

(4) A relevant device falling within Class III may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex II, or

(ii) Annex III, together with Annex IV or V;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and

(c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

[F4(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.**]**

Textual Amendments

F4 Reg. 13(5)(6) added (1.4.2004) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(b), **6**

Procedures for systems and procedure packs, and for devices to be sterilised before use

14.—(1) Subject to paragraph (3), no person shall supply a system or procedure pack (if that supply is also a placing on the market, or if that supply is of a system or procedure pack that has been placed on the market) unless—

(a) the medical devices in that system or procedure pack are for use within their intended purpose and within the limits of use specified by their manufacturer;

(b) the person who places or has placed it on the market has drawn up a declaration that—

(i) he has verified the mutual compatibility of the medical devices in that system or procedure pack in accordance with the manufacturers' instructions, and he has carried out his operations in accordance with these instructions,

(ii) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers, and

(iii) his production of the system or procedure pack is subjected to appropriate methods of internal control and inspection,

and that declaration is true at the time it is made and continues to be true.

(2) Subject to paragraph (3), no person shall supply—

(a) a system or procedure pack which was sterilised before being placed on the market; or

(b) a relevant device (including a system or procedure pack) which is designed by its manufacturer to be sterilised before use,

(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 the person who places, or who has placed, the device on the market satisfies the conditions set out in paragraph (4).

(3) Paragraphs (1) and (2)(a) shall only apply to a system or procedure pack if, by virtue of regulation 12(3), regulation 10 does not apply to that system or procedure pack.

(4) The conditions referred to in paragraph (2) are that the person shall—

(a) fulfil the obligations imposed by either Annex IV, Annex V or Annex VI that relate to the obtaining of sterility; and

(b) if the device has been sterilised, make a written declaration that sterilisation has been carried out in accordance with the manufacturer's instructions.

(5) Where a conformity assessment procedure is carried out in respect of a relevant device (including a device which is a system or procedure pack) pursuant to this regulation—

(a) no person shall affix a CE marking to that device as a result of that procedure; and

(b) no person shall 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 it is accompanied by the information referred to in Section 13 of Annex I, which shall include, where appropriate, the information supplied by the manufacturers of the devices which have been put together.

(6) The declarations referred to in paragraph (1)(b) and (4)(b) shall be kept available for the Secretary of State by the person responsible for placing the product on the market for a period of five years.

Procedures for custom-made general medical devices

15. No person shall supply a custom-made device (if that supply is also a placing on the market, or if that supply is of a custom-made device that has been placed on the market) unless its manufacturer or his authorised representative—

(a) has drawn up a statement containing the information required by Sections 1, 2 and 2.1 of Annex VIII;

(b) has undertaken to keep available for the Secretary of State documentation allowing an understanding of the design, manufacture and performances of the device, including the expected performances, so as to allow assessment of conformity of the device with the requirements of Directive 93/42; and

(c) takes all necessary measures to ensure that the manufacturing process ensures that each device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.1 of Annex VIII; and

(d) keeps available for the Secretary of State, for a minimum period of five years, the information contained in the statement referred to in paragraph (a) and in the undertaking referred to in paragraph (b).

Procedures for general medical devices for clinical investigations

16.—(1) Subject to paragraph (2), no person shall supply a relevant device (if that supply is also a making available of the device) for the purposes of a clinical investigation in the United Kingdom unless, before he does so, the manufacturer of the device or his authorised representative has given at least 60 days prior notice in writing to the Secretary of State of the intended investigation, in the form of—

(a) subject to paragraph (3), the statement required by Sections 1 and 2 of Annex VIII; and

(b) an undertaking to keep available for the Secretary of State the documentation referred to in Section 3.2 of Annex VIII for a minimum period of five years.

(2) Paragraph (1) shall not apply in respect of an intended clinical investigation of a relevant device that bears a CE marking otherwise than in breach of regulation 13, unless the aim of the

intended investigation is to determine whether the device may be used for a purpose other than that in respect of which it was CE marked in accordance with regulation 13.

(3) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex VIII need not be provided to the Secretary of State at least 60 days prior to the intended investigation, but if it is not provided at least 60 days prior to the intended investigation, it must be provided to the Secretary of State by the manufacturer or his authorised representative as soon as it becomes available.

(4) If, within 60 days of the formal acceptance by the Secretary of State of the notice in writing given pursuant to paragraph (1), the Secretary of State gives written notice to the manufacturer or authorised representative (whichever gave the notice pursuant to paragraph (1)) that, on grounds of public health or public policy, the relevant device should not be made available for the purposes of the intended investigation, no person shall supply the relevant device (if that supply is also a making available of the device) for those purposes.

(5) The Secretary of State may, in respect of notice in writing given by a manufacturer or his authorised representative pursuant to paragraph (1), give written notice to the manufacturer or his authorised representative—

(a) that the relevant device may be made available for the purposes of the intended investigation; or

(b) if the ethics committee opinion required under Section 2.2 of Annex VIII is not available, that the relevant device may be made available for the purposes of the intended investigation once a favourable opinion in respect of the investigational plan for the intended investigation has been delivered by the committee.

(6) A written notice pursuant to paragraph (5) may—

(a) where appropriate be given subject to conditions imposed by the Secretary of State, which are to be included in the notice;

(b) at any time be withdrawn on grounds of public health or public policy by the Secretary of State.

(7) Where a written notice pursuant to paragraph (5) in respect of a relevant device has been withdrawn by the Secretary of State—

(a) further clinical use of the relevant device in the investigation is prohibited; and

(b) no person shall supply that relevant device for the purposes of the investigation (if that supply is also a making available of the device),

unless the Secretary of State issues a further written notice pursuant to that paragraph stating that the relevant device may again be made available for the purposes of the investigation.

(8) The manufacturer of a relevant device intended for clinical investigation to which paragraph (1) applies, or his authorised representative, shall—

(a) take all necessary measures to ensure that the manufacturing process for the relevant device produces devices manufactured in accordance with the documentation referred to in the first paragraph of Section 3.2 of Annex VIII;

(b) authorise the assessment, including audit where necessary, of the effectiveness of the measures which he takes pursuant to this regulation; and

(c) keep the information contained in the statement and the undertaking referred to in paragraph (1) for a minimum period of five years.

(9) The grounds of public health or public policy referred to in paragraph (4) or (6)(b) are met, amongst other reasons, if—

(a) the manufacturer or his authorised representative does not authorise an assessment by the Secretary of State, whether by means of an audit, an inspection or otherwise, of the effectiveness of the measures referred to in paragraph (8); or

(b) the manufacturer or his authorised representative does not make available to the Secretary of State documentation which he has undertaken to keep available in accordance with paragraph (1)(b).

(10) No person shall conduct a clinical investigation of a relevant device—

(a) otherwise than in accordance with Annex X; and

(b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (6)(a),

and if a clinical investigation is conducted in respect of a relevant device, the manufacturer of that device or his authorised representative shall keep available for the Secretary of State the report referred to in Section 2.3.7 of Annex X.

Manufacturers etc. and conformity assessment procedures for general medical devices

17.—(1) A manufacturer of a relevant device or, where applicable, his authorised representative who is required to follow, or follows or has followed a conformity assessment procedure set out in Directive 93/42 shall observe the manufacturer's obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, his authorised representative shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 93/42 at an intermediate stage of manufacture of the device.

(3) Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep available the technical documentation referred to in—

(a) Section 6.3 of Annex II or Section 7.4 of Annex III shall fall upon the person responsible for placing on the market the device to which the documentation relates or, where appropriate, upon the importer referred to in Section 13.3(a) of Annex I;

(b) Section 2 of Annex VII shall fall upon the person who places on the market the device to which the documentation relates.

[[F5](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.**]**

Textual Amendments

F5 Reg. 17(4)(5) added (1.4.2004) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(b), **7**

UK notified bodies and the conformity assessment procedures for general medical devices

18.—(1) A UK notified body which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

(a) take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 93/42 at an intermediate stage of manufacture of the device;

(b) take account of any relevant information relating to the characteristics and performance of that device, including in particular the results of any relevant tests and verification relating to that device already carried out under the laws or administrative provisions in force before 1st January 1995 in any EEA State; and

(c) lay down, by common accord with the manufacturer or his authorised representative, the time limits for completion of the assessment and verification operations referred to in Annex II to IV.

(2) Where a UK notified body takes a decision in accordance with Annex II or III, they shall specify the period of validity of the decision, which initially shall be for a period of not more than five years.

(3) Where a UK notified body and a manufacturer or his authorised representative have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or his authorised representative, extend the period of validity of the decision for further periods of up to five years, each such period commencing on the expiry of the previous period.

[[F6](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.**]**

Textual Amendments

F6 Reg. 18(4) added (1.9.2003) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **8**

Registration of persons placing general medical devices on the market

19.—(1) Subject to paragraph (6), for the purpose of enabling the Secretary of State to exercise his functions under these Regulations, any person to whom this paragraph applies shall—

(a) inform the Secretary of State of the address of his registered place of business; and

(b) supply the Secretary of State with a description of each category of device concerned.

(2) Paragraph (1) applies to—

(a) a manufacturer with a registered place of business in the United Kingdom who, under his own name, places on the market in the United Kingdom a relevant device which is a Class 1 device or a custom-made device, other than a system or procedure pack which is not CE marked; and

(b) a person with a registered place of business in the United Kingdom who sterilises before use relevant devices designed by their manufacturer to be sterilised before use.

(3) Subject to paragraph (6), for the purpose of enabling the Secretary of State to exercise his functions under these Regulations, any person with a registered place of business in the United Kingdom who places a device mentioned in paragraph (2) on the market in the United Kingdom on

behalf of a manufacturer who does not have a registered place of business in the Community or in a State which is a Party to an Association Agreement shall inform the Secretary of State of—

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

(b) the category of device; and

(c) in the case of an authorised representative of the manufacturer, the fact that he is the manufacturer's authorised representative, and he shall furnish the Secretary of State with sufficient evidence that he is an authorised representative of the manufacturer.

(4) Subject to paragraph (6), for the purpose of enabling the Secretary of State to exercise his functions under these Regulations, any person with a registered place of business in the United Kingdom who places a system or procedure pack which is not CE marked on the market in the United Kingdom, or who sterilises systems or procedure packs before they are placed on the market, shall—

(a) inform the Secretary of State of the address of that registered place of business; and

(b) supply the Secretary of State with descriptions of the devices which are included in any such system or procedure pack in a manner sufficient to identify them.

(5) Subject to paragraph (6), for the purpose of enabling the Secretary of State to exercise his functions under these Regulations, any person with a registered place of business in the United Kingdom who places a relevant device which is a Class IIb or III device on the market in the United Kingdom (including the authorised representative of a manufacturer of a Class IIb or III device who does not have a registered place of business in the Community or in a State which is a Party to an Association Agreement) shall, if the Secretary of State so requests, supply the Secretary of State with all data allowing for the identification of the device together with the label and the instructions for use for when the device is put into service within the United Kingdom.

(6) Registration under this regulation is not required if—

(a) the device or pack was first placed on the market in a State which is a Party to an Association Agreement (if that Agreement contains measures relating to the mutual recognition of the results of conformity assessment undertaken in respect of that device); and

(b) the manufacturer or his authorised representative has already registered with the competent authorities of that State.

[F7Additional 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.**]**

Textual Amendments

F7 Reg. 19A inserted (1.4.2004) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(b), **9**

Status:
Point in time view as at 01/09/2007.

Changes to legislation:
The Medical Devices Regulations 2002, PART II is up to date with all changes known to be in force on or before 17 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.