STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART III

Active Implantable Medical Devices

Interpretation of Part III

20.—(1) In this Part, unless the context otherwise requires—

"custom-made device" means an active implantable medical device that is—

(a) manufactured specifically in accordance with a medical specialist's written prescription which gives, under his responsibility, specific characteristics as to its design; and

(b) intended to be used only for a particular patient; and

"relevant device" shall be construed in accordance with regulation 21.

(2) In this Part, unless the context otherwise requires, a reference to a numbered article or Annex is to the article or Annex of Directive 90/385 bearing that number.

Scope of Part III

21. The requirements of this Part in respect of relevant devices apply in respect of active implantable medical devices and accessories to such devices, except for devices that come within the scope of Directive 90/385 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, and

(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; and

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

Essential requirements for active implantable medical devices

22.—(1) Subject to regulation 26, 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 1 which apply to it.

(2) Subject to regulation 26, 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 also been placed on the market or put into service,

unless that device meets those essential requirements set out in Annex 1 which apply to it.

Determining compliance of active implantable medical devices with relevant essential requirements

23.—(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) Any—

(a) determination that a relevant device complies with any of the essential requirements set out in paragraphs 1 to 5 of Annex 1; and

(b) evaluation of side effects or undesirable effects for the purposes of determining whether or not a relevant device complies with any of the essential requirements,

shall be based in particular on clinical data, the adequacy of which is based on the collation of scientific literature or the results of clinical investigations referred to in paragraph 1 of Annex 7, and any determination as to whether or not a relevant device complies with any other essential requirements may be based on such data.

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

(a) the essential requirements specified in paragraph 14 of Annex 1 are complied with only if the particulars there specified are in English (whether or not they are also in another language and whether or not the device is for professional use); and

(b) the essential requirements specified in paragraph 13 of Annex 1, so far as they relate to instructions required for the operation of a device in paragraph 15 of Annex 1, are complied with only if—

(i) the 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 the device does not comply with that requirement.

(5) A custom-made device in respect of which the conditions specified in Annex 6 are satisfied and which is accompanied by the statement referred to in paragraph 1 of Annex 6 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) A device intended for clinical investigation in respect of which—

(a) the conditions specified in Annex 7 are satisfied;

(b) notice has been given under regulation 29(1); and

(c) either—

(i) no notice has been given under regulation 29(3) within the period of 60 days there referred to, or

(ii) notice has been given under regulation 29(4),

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.

CE marking of active implantable medical devices

24.—(1) Subject to regulation 26, no person shall place on the market or put into service a relevant device unless that device or its sterile pack bears a CE marking which—

(a) meets the requirements set out in Annex 9;

(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 regulation 26, no person shall supply a relevant device unless that device or its sterile pack bears a CE marking which—

(a) meets the requirements set out in Annex 9;

(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 regulation 26, 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 9, appears on—

(a) where appropriate, 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 regulation 26, 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 9, appears on—

(a) where appropriate, 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) where appropriate, 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 active implantable medical devices that come within the scope of more than one Directive

25. Where a relevant device comes within the scope of Directive 90/385 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 90/385;

(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 90/385, as published in the Official Journal of the European Communities, are given in the documents, notices or instructions accompanying the device, and in a manner in which those particulars are accessible without it being necessary to destroy the packaging which keeps the device sterile.

Exemptions from regulations 22 and 24

26.—(1) A relevant device 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 90/385 or these Regulations.

(2) Regulation 24 shall not apply to a custom-made device or a device intended for clinical investigation.

(3) Regulations 22 and 24 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 active implantable medical devices

27. A relevant device may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex 2, or

(ii) Annex 3, together with Annex 4 or 5;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 90/385 that apply to it; and

(c) ensures that the device meets the provisions of Directive 90/385 which apply to it.

Procedures for custom-made active implantable medical devices

28. 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 the statement containing the information required by Section 2.1 of Annex 6;

(b) has undertaken to keep available for the Secretary of State the documentation referred to in Section 3.1 of Annex 6;

(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 6; and

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

Procedures for active implantable medical devices for clinical investigations

29.—(1) 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 (2), the statement required by Section 2.2 of Annex 6; and

(b) an undertaking to keep available for the Secretary of State the documentation referred to in Section 3.1 and 3.2 of Annex 6.

(2) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex 6 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.

(3) 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.

(4) 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) if the ethics committee opinion required under Section 2.2 of Annex 6 is favourable, 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 6 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.

(5) A written notice pursuant to paragraph (4) 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.

(6) Where a written notice pursuant to paragraph (4) 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.

(7) 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 ensures that each device manufactured according to that process conforms to the documentation referred to in the first paragraph of Section 3.1, and the first paragraph of Section 3.2, of Annex 6;

(b) keep available for the Secretary of State the information contained in the statement and the undertaking referred to in paragraph (1); and

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

(8) The grounds of public health or public policy referred to in paragraphs (3) and (5)(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 (7); 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).

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

(a) otherwise than in accordance with Annex 7; and

(b) otherwise than in accordance with any conditions imposed by the Secretary of State pursuant to paragraph (5)(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 7.

Manufacturers etc. and conformity assessment procedures for active implantable medical devices

30.—(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 90/385 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 90/385 at an intermediate stage of manufacture of the device.

UK notified bodies and the conformity assessment procedures for active implantable medical devices

31.—(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 90/385 at an intermediate stage of manufacture of the device; and

(b) 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 2 or 3.

(2) Where a UK notified body takes a decision in accordance with Annex 2 or 3, 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.