STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART V

Notified Bodies, Conformity Assessment Bodies and Marking of Products

[F1Interpretation 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.**]**

Textual Amendments

F1 Reg. 44A inserted (1.9.2003) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **12**

Designation etc. of UK notified bodies

45.—(1) The Secretary of State may designate for the purposes of article 11 of Directive 90/385, article 16 of Directive 93/42 or article 15 of Directive 98/79 any corporate or other body as a body which is to carry out any of the tasks of a notified body, and, if he so designates a body (referred to in these Regulations as a "UK notified body"), he shall designate the tasks which it is to carry out.

(2) A body may be designated under paragraph (1) as a body which is to carry out tasks of a notified body only if—

(a) in so far as it is to be designated as a body which is to carry out tasks included in Directive 90/385, it is a body in respect of which the criteria for the designation of notified bodies set out in Annex 8 of that Directive**[**F2, read with Regulation (EU) No 722/2012,**]** are met;

(b) in so far as it is to be designated as a body which is to carry out tasks included in Directive 93/42, it is a body in respect of which the criteria for the designation of notified bodies set out in Annex XI of that Directive**[**F3, read with **[**F4Regulation (EU) No 722/2012**]**,**]** are met;

(c) in so far as it is to be designated as a body which is to carry out tasks included in Directive 98/79, it is a body in respect of which the criteria for the designation of notified bodies set out in Annex IX of that Directive are met; and

(d) in so far as it needs to be able to fulfil the functions of an importing Party arising out of the Mutual Recognition Agreements, it is able to do so.

(3) The Secretary of State may refuse to designate a body under paragraph (1) if it fails to pay any fee payable under Part VI in connection with an application for designation.

(4) The Secretary of State may vary the tasks that a UK notified body may carry out, and if he does, those varied tasks will be the tasks which it is designated to carry out.

(5) The Secretary of State may place a restriction in relation to, or withdraw, any designation of a body under paragraph (1) if—

(a) the body so requests;

(b) he considers that it is no longer a body in respect of which the applicable criteria for designation set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42, **[**F5both read with Regulation (EU) No 722/2012**]** or Annex IX of Directive 98/79 are met; or

(c) he considers that the body is not capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil,

and the Secretary of State may also withdraw any designation of a body under paragraph (1) if it fails to pay any fee payable under Part VI.

(6) Before—

(a) effecting a variation under paragraph (4); or

(b) restricting or withdrawing a designation under paragraph (5),

otherwise than at the notified body's request, the Secretary of State shall give to the notified body an opportunity to make representations to him in writing and shall take into account any such representations as are made.

(7) For the purpose of deciding whether or not a body is one in respect of which the criteria set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42, **[**F6both read with Regulation (EU) No 722/2012**]** or Annex IX of Directive 98/79 are met as respects the tasks which the body wants to carry out, or carries out, or for the purposes of deciding whether or not a body is capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, the Secretary of State may arrange for the inspection of—

(a) any premises occupied, or plant or equipment used, in connection with the carrying out of any such task; or

(b) any premises occupied, or plant or equipment used, by a manufacturer where the body is undertaking any task in relation to that manufacturer,

and may take into account for the purposes of his decision the results of any such inspection and any refusal to afford him such facilities or assistance as he may reasonably require in order to carry out any such inspection.

(8) The Secretary of State may request that a UK notified body supply to him any or all relevant information and documents, including budgetary documents, necessary—

(a) to enable him to verify that the body meets the criteria set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42, **[**F7both read with Regulation (EU) No 722/2012**]**, or Annex IX of Directive 98/79; or

(b) for the purposes of deciding whether or not the body is capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil,

and the body shall supply to him any and all relevant information or documents so requested.

Textual Amendments

F2 Words in reg. 45(2)(a) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **14(2)**

F3 Words in reg. 45(2)(b) inserted (1.9.2003) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **13(a)**

F4 Words in reg. 45(2)(b) substituted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **14(3)**

F5 Words in reg. 45(5)(b) substituted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **14(4)**

F6 Words in reg. 45(7) substituted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **14(4)**

F7 Words in reg. 45(8) substituted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **14(4)**

Choice of notified bodies and conformity assessment bodies

46. Where a conformity assessment procedure involves the intervention of a notified body, including work which may be carried out by a third country conformity assessment body, the manufacturer of a device or his authorised representative may apply to any notified body or third country conformity assessment body to carry out tasks under that procedure which are within the framework of tasks which the body is designated to carry out.

General matters relating to UK notified bodies

47.—(1) A UK notified body to which an application has been made by a manufacturer or his authorised representative to perform the functions of a notified body under a conformity assessment procedure set out in the Medical Devices Directives shall perform those functions, in accordance with the requirements of the procedure, if those functions are within the framework of tasks which the body is designated to carry out.

(2) Where a manufacturer or his authorised representative has supplied information or data to a UK notified body in the course of a conformity assessment procedure, that body may, where duly justified, require the manufacturer to provide any additional information or data which it considers necessary for the purposes of that procedure.

(3) The information, data and correspondence that a manufacturer or his authorised representative supplies to a notified body in the course of a conformity assessment procedure set out in the Medical Devices Directives shall, if the notified body is within the United Kingdom, be in English or some other Community language acceptable to the notified body concerned.

(4) A UK notified body shall, as respects a medical device which it has assessed [F8]..., inform all other notified bodies and the Secretary of State of—

(a) all certificates suspended or withdrawn; and

(b) on request, all certificates issued or refused,

and shall also make available to them, on request, any or all additional relevant information.

(5) Where a UK notified body finds, as respects a medical device which it has assessed [F8]..., that—

(a) the applicable requirements of the Medical Devices Directives have not been met or are no longer met; or

(b) a certificate issued by it should not have been issued,

it may (having regard in particular to the principle of proportionality and the ability of the manufacturer to take appropriate corrective measures) suspend or withdraw the certificate issued in respect of that device or place restrictions on it, and in such cases, or in cases where the notified body is aware of circumstances in which the Secretary of State may need to take action pursuant to regulation 61, the notified body shall inform the Secretary of State thereof.

(6) The Secretary of State may request that a UK notified body supply to him any information and documents that the Secretary of State may, having regard to the terms of the Mutual Recognition Agreements, need to supply to a Party to the Mutual Recognition Agreements, and the body shall supply to him any and all information or documents so requested.

(8) A UK notified body shall provide conformity assessment bodies with all the information it is required to provide to those bodies under the Mutual Recognition Agreements.

F9(9) . . . . . .

F9(10) . . . . . .

Textual Amendments

F8 Words in reg. 47(4)(5) omitted (21.3.2010) by virtue of The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **16**

F9 Reg. 47(9)(10) omitted (21.10.2013) by virtue of The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **15**

Designation etc. of EC conformity assessment bodies

48.—(1) The Secretary of State may designate for the purposes of the Mutual Recognition Agreements any corporate or other body as a body which is to carry out any of the tasks of a European Community conformity assessment body, and, if he so designates a body (referred to in these Regulations as an "EC CAB"), he shall designate the tasks which it is to carry out.

(2) A body may be designated under paragraph (1) as a body which is to carry out tasks of an EC CAB only if the Secretary of State considers that the body is capable of fulfilling the functions of an EC CAB arising out of the Mutual Recognition Agreements which it needs to be able to fulfil.

(3) The Secretary of State may refuse to designate a body under paragraph (1) if it fails to pay any fee payable under Part VI in connection with an application for designation.

(4) The Secretary of State may vary the tasks that an EC CAB may carry out, and if he does, those varied tasks will be the tasks which it is designated to carry out.

(5) The Secretary of State may place a restriction in relation to, or withdraw, any designation of a body under paragraph (1) if—

(a) the body so requests; or

(b) he considers that the body is not capable of fulfilling the functions of an EC CAB arising out of the Mutual Recognition Agreements which it needs to be able to fulfil,

and the Secretary of State may also withdraw any designation of a body under paragraph (1) if it fails to pay any fee payable under Part VI.

(6) Before—

(a) effecting a variation under paragraph (4); or

(b) restricting or withdrawing a designation under paragraph (5),

otherwise than at the EC CAB's request, the Secretary of State shall give to the EC CAB an opportunity to make representations to him in writing and shall take into account any such representations as are made.

(7) For the purpose of deciding whether or not a body is capable of fulfilling the functions of an EC CAB arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, the Secretary of State may arrange for the inspection of—

(a) any premises occupied, or plant or equipment used, in connection with the carrying out of any such task; or

(b) any premises occupied, or plant or equipment used, by a manufacturer where the body is undertaking any task in relation to that manufacturer,

and may take into account for the purposes of his decision the results of any such inspection and any refusal to afford him such facilities or assistance as he may reasonably require in order to carry out any such inspection.

(8) The Secretary of State may request that an EC CAB supply to him any or all relevant information and documents, including budgetary documents, necessary for the purposes of deciding whether or not the body is capable of fulfilling the functions of an EC CAB arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, and the body shall supply to him any and all relevant information or documents so requested.

Fees charged by UK notified bodies and EC conformity assessment bodies

49.—(1) A UK notified body or EC CAB may charge a fee in accordance with paragraphs (2), (3) and (4) for anything done in, or in connection with—

(a) in the case of a UK notified body, performing the functions of a notified body or an importing Party under the Medical Devices Directives or the Mutual Recognition Agreements in respect of a conformity assessment procedure set out in the Medical Devices Directives; and

(b) in the case of an EC CAB, performing the functions of an EC CAB arising out of the Mutual Recognition Agreements in respect of a conformity assessment procedure for a medical device.

(2) Except as provided for by paragraph (3), the fee charged in respect of anything done shall not exceed an amount which reasonably represents the cost incurred, or to be incurred, in doing it.

(3) Where the UK notified body or EC CAB charging the fee is a body the activities of which are carried on for profit, the fee may include an amount representing a profit which is reasonable in the circumstances, having regard to—

(a) the character and extent of the work done or to be done by the notified body; and

(b) the commercial rate normally charged in respect of profit for that work or similar work.

(4) The UK notified body or EC CAB may require payment of the fee, or a reasonable estimate of the fee, in advance of carrying out the work in respect of which the fee is payable and as a condition of doing that work.

Products incorrectly marked with a notified body or conformity assessment body number

50.—(1) No person shall—

(a) affix a notified body or conformity assessment body number to a medical device if that body has not carried out an assessment in respect of that device for that person;

(b) supply a medical device (if that supply is also a placing on the market, or if that supply is of a device which has been placed on the market) which has affixed to it a notified body or conformity assessment body number if that body—

(i) has not carried out an assessment in respect of that device, or has not carried out that assessment for the person responsible for placing the device on the market, or

(ii) has had its designation as a notified body or conformity assessment body withdrawn.

(2) No person shall provide information comprising a notified body or conformity assessment body number on a medical device, the instructions for use for a medical device, or the sales packaging for a medical device if that device—

(a) is being or has been placed on the market; and

(b) the notified body or conformity assessment body—

(i) has not carried out an assessment in respect of that device, or has not carried out that assessment for the person responsible for placing the device on the market, or

(ii) has had its designation as a notified body or conformity assessment body withdrawn.

(3) Where the sectoral annex on medical devices in a Mutual Recognition Agreement under which a conformity assessment body was designated states that the annex does not apply to devices of a particular class or description, no person may supply a medical device of that class or description bearing the number of that conformity assessment body (if that supply is also a placing on the market or putting into service or is of a device that has been placed on the market or put into service) unless—

(a) an assessment has been carried out on that device for the person responsible for placing it on the market or putting it into service by a notified body; and

(b) the device bears the notified body number of that notified body.

(4) For the purposes of this regulation, a notified body shall be taken to have carried out an assessment in respect of a device if it has endorsed a report prepared by a third country conformity assessment body in respect of that device.

Products incorrectly marked with a CE marking

51.—(1) No person shall—

(a) affix the CE marking for a medical device to a product which is not a medical device; or

(b) supply a product (if that supply is also a placing on the market, or if that supply is of a product which has been placed on the market) which has affixed to it the CE marking for a medical device if that product is not a medical device.

(2) No person shall provide information comprising a CE marking for a medical device on a product, the instructions for use for a product, or the sales packaging for a product if the product is not a medical device.

Status:
Point in time view as at 21/10/2013.

Changes to legislation:
The Medical Devices Regulations 2002, PART V is up to date with all changes known to be in force on or before 10 June 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.