STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART V U.K.

[F1Notified Bodies][F1Approved Bodies], Conformity Assessment Bodies and Marking of Products

Textual Amendments

F1 Words in Pt. 5 heading substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(2)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F2Interpretation of Part V U.K.

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

F2 Reg. 44A inserted (1.9.2003) by The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **12**

[F3Meaning of approved body and UK notified body E+W+S

A45.—(1) An approved body is a conformity assessment body which—

(a) has been designated by the Secretary of State pursuant to the procedure set out in regulation 45 (designation etc. of approved bodies); or

(b) immediately before IP completion day was a UK notified body in respect of which the Secretary of State has taken no action under regulation 45(5) to withdraw a designation.

(2) In this regulation—

"UK notified body" means a body which the Secretary of State had before IP completion day notified to the European Commission in accordance with Article 3(7) of Commission Implementing Regulation (EU) 920/2013 or under Article 15 of Directive 98/79.".**]**

Textual Amendments

F3 Reg. A45 inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(3)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47(3)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Designation etc. of [F4approved bodies] E+W+S

45.—(1) The Secretary of State may designate for the purposes of **[**F5these Regulations**]** any corporate or other body as a body which is to carry out any of the tasks of **[**F6an approved body**]**, and, if he so designates a body (referred to in these Regulations as **[**F7an "approved 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 **[**F8an approved body**]** only if—

(a) in so far as it is to be designated as a body which is to carry out tasks included in **[**F9Part III**]**, it is a body in respect of which the criteria for the designation of **[**F10approved bodies set out in Annex 8 of Directive 90/385**][**F11, 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 **[**F12Part II**]**, it is a body in respect of which the criteria for the designation of **[**F13approved bodies set out in Annex XI of Directive 93/42**][**F14, read with **[**F15Regulation (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 **[**F16Part IV**]**, it is a body in respect of which the criteria for the designation of **[**F17approved bodies set out in Annex IX of Directive 98/79**]** are met; and

(d) in so far as it needs to be able to fulfil the functions of an importing Party arising out of **[**F18a mutual recognition agreement**]**, 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 **[**F19an approved 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, **[**F20both 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 **[**F21a mutual recognition agreement**]** 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 **[**F22the approved body's request**]**, the Secretary of State shall give to the **[**F23approved 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, **[**F24both 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 **[**F25a mutual recognition agreement**]** 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 **[**F26an approved 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, **[**F27both 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 **[**F28a mutual recognition agreement**]** which it needs to be able to fulfil,

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

Extent Information

E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F4 Words in reg. 45 heading substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F5 Words in reg. 45(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(b)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F6 Words in reg. 45(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(b)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F7 Words in reg. 45(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(b)(iii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F8 Words in reg. 45(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F9 Word in reg. 45(2)(a) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(d)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F10 Words in reg. 45(2)(a) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(d)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F11 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)**

F12 Words in reg. 45(2)(b) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(e)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F13 Words in reg. 45(2)(b) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(f)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F14 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)**

F15 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)**

F16 Words in reg. 45(2)(c) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(f)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F17 Words in reg. 45(2)(c) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(f)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F18 Words in reg. 45(2)(d) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(g)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F19 Words in reg. 45(4) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(h)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F20 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)**

F21 Words in reg. 45(5)(c) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F22 Words in reg. 45(6) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(j)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F23 Words in reg. 45(6) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(j)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F24 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)**

F25 Words in reg. 45(7) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(k)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F26 Words in reg. 45(8) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(l)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F27 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)**

F28 Words in reg. 45(8)(b) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(4)(l)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

Designation etc. of UK notified bodies N.I.

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 **[**[F87]with respect to devices to be placed on

the market in Northern Ireland**]**, 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 **[**F88, 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 **[**F89, read with **[**F90Regulation (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, **[**F91both 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, **[**F92both 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, **[**F93both 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.

Extent Information

E9 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F87 Words in reg. 45(1) inserted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 16**

F88 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)**

F89 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)**

F90 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)**

F91 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)**

F92 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)**

F93 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)**

[F29**Choice of approved bodies and conformity assessment bodies]** E+W+S

46. Where a conformity assessment procedure involves the intervention of **[**F30an approved body**]**, including work which may be carried out by a third country conformity assessment body, the manufacturer of a device or **[**F31the manufacturer's UK responsible person**]** may apply to **[**F32any approved 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.

Extent Information

E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F29 Reg. 46 heading substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(5)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F30 Words in reg. 46 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(5)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F31 Words in reg. 46 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(5)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F32 Words in reg. 46 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(5)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

Choice of notified bodies and conformity assessment bodies N.I.

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.

Extent Information

E10 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F33General matters relating to approved bodies] E+W+S

47.—(1) **[**F34An approved body**]** to which an application has been made by a manufacturer or **[**F35the manufacturer's UK responsible person**]** to perform the functions of **[**F36an approved body**]** under a conformity assessment procedure set out in **[**F37these Regulations**]** 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 **[**F38the manufacturer's UK responsible person**]** has supplied information or data to **[**F39an approved 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 **[**F40the manufacturer's UK responsible person supplies to an approved body**]** in the course of a conformity assessment procedure set out in **[**F41these Regulations**]** shall, F42..., be in English F43....

(4) **[**F44An approved body**]** shall, as respects a medical device which it has assessed F45..., inform all **[**F46other approved 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 **[**F47an approved body**]** finds, as respects a medical device which it has assessed F45..., that—

(a) the applicable requirements of **[**F48these Regulations**]** 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 **[**F49approved body**]** is aware of circumstances in which the Secretary of State may need to take action pursuant to regulation 61, the **[**F49approved body**]** shall inform the Secretary of State thereof.

(6) The Secretary of State may request that **[**F50an approved body**]** supply to him any information and documents that the Secretary of State may, having regard to the terms of **[**F51a mutual recognition agreement**]**, need to supply to a Party to **[**F51a mutual recognition agreement**]**, and the body shall supply to him any and all information or documents so requested.

(8) **[**F52An approved body**]** shall provide conformity assessment bodies with all the information it is required to provide to those bodies under **[**F53a mutual recognition agreement**]**.

F54(9) . . . . . .

F54(10) . . . . . .

Extent Information

E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F33 Reg. 47 heading substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F34 Words in reg. 47(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(b)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F35 Words in reg. 47(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(b)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F36 Words in reg. 47(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(b)(iii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F37 Words in reg. 47(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(b)(iv)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F38 Words in reg. 47(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(c)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F39 Words in reg. 47(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(c)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F40 Words in reg. 47(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(d)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F41 Words in reg. 47(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(d)(iii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F42 Words in reg. 47(3) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(d)(iii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F43 Words in reg. 47(3) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(d)(iv)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F44 Words in reg. 47(4) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(e)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F45 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**

F46 Words in reg. 47(4) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(e)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F47 Words in reg. 47(5) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(f)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F48 Words in reg. 47(5)(a) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(f)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F49 Words in reg. 47(5) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(f)(iii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F50 Words in reg. 47(6) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(g)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F51 Words in reg. 47(6) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(g)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F52 Words in reg. 47(8) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(h)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F53 Words in reg. 47(8) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(6)(h)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F54 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**

General matters relating to UK notified bodies N.I.

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 [F94]..., 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 [F94]..., 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.

[F95](9) . . . . . .

[F95](10) . . . . . .

Extent Information

E11 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F94 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**

F95 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**

[F55Register of approved bodies E+W+S

47A.—(1) The Secretary of State must ensure that—

(a) each approved body is assigned an identification number; and

(b) there is a register of—

(i) approved bodies;

(ii) their approved body identification number;

(iii) the tasks for which they have been designated; and

(iv) any restrictions on those tasks.

(2) The Secretary of State must ensure that the register referred to in paragraph (1) is maintained and made publicly available.

(3) The Secretary of State may authorise the United Kingdom Accreditation Service to compile and maintain the register in accordance with paragraph (1)(b).**]**

Extent Information

E4 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F55 Reg. 47A inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(7)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47(7)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F96Register of UK notified bodies N.I.

47A.—(1) The Secretary of State must ensure that—

(a) each notified body established in the United Kingdom is assigned an identification number; and

(b) there is a register of—

(i) notified bodies established in the United Kingdom;

(ii) their notified body identification number;

(iii) the tasks for which they have been notified;

(iv) any restrictions on those tasks.

(2) The Secretary of State must ensure that the register referred to in paragraph (1) is maintained and made publicly available.

(3) The Secretary of State may authorise the United Kingdom Accreditation Service to compile and maintain the register in accordance with paragraph (1)(b).**]**

Extent Information

E12 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F96 Reg. 47A inserted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 17**

Designation etc. of F56... conformity assessment bodies E+W+S

48.—(1) The Secretary of State may designate for the purposes of **[**F57a mutual recognition agreement**]** any corporate or other body as a body which is to carry out any of the tasks of a F58... conformity assessment body, and, if he so designates a body (referred to in these Regulations as **[**F59a "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 **[**F60a CAB**]** only if the Secretary of State considers that the body is capable of fulfilling the functions of **[**F60a CAB**]** arising out of **[**F61a mutual recognition agreement**]** 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 **[**F62a 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 **[**F63a CAB**]** arising out of **[**F64a mutual recognition agreement**]** 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 F65... CAB's request, the Secretary of State shall give to the F65... 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 **[**F66a CAB**]** arising out of **[**F67a mutual recognition agreement**]** 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 **[**F68a 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 **[**F68a CAB**]** arising out of **[**F69a mutual recognition agreement**]** which it needs to be able to fulfil, and the body shall supply to him any and all relevant information or documents so requested.

Extent Information

E5 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F56 Word in reg. 48 heading omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(8)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F57 Words in reg. 48(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(8)(b)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F58 Words in reg. 48(1) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(8)(b)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F59 Words in reg. 48(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(8)(b)(iii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F60 Words in reg. 48(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(8)(c)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F61 Words in reg. 48(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(8)(c)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F62 Words in reg. 48(4) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(8)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F63 Words in reg. 48(5)(b) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(8)(e)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F64 Words in reg. 48(5)(b) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(8)(e)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F65 Word in reg. 48(6) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(8)(f)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F66 Words in reg. 48(7) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(8)(g)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F67 Words in reg. 48(7) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(8)(g)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F68 Words in reg. 48(8) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(8)(h)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F69 Words in reg. 48(8) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(8)(h)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

Designation etc. of F97... conformity assessment bodies N.I.

48.—(1) The Secretary of State may designate for the purposes of **[**F98a UK mutual recognition agreement**]** any corporate or other body as a body which is to carry out any of the tasks of a F99... conformity assessment body, and, if he so designates a body (referred to in these Regulations as **[**F100a "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 **[**F101a CAB**]** only if the Secretary of State considers that the body is capable of fulfilling the functions of **[**F101a CAB**]** arising out of **[**F102a UK mutual recognition agreement**]** 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 **[**F103a 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 **[**F104a CAB**]** arising out of **[**F105a UK mutual recognition agreement**]** 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 F106... CAB's request, the Secretary of State shall give to the F106... 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 **[**F107a CAB**]** arising out of **[**F108a UK mutual recognition agreement**]** 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 **[**F109a 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 **[**F109a CAB**]** arising out of **[**F110a UK mutual recognition agreement**]** which it needs to be able to fulfil, and the body shall supply to him any and all relevant information or documents so requested.

Extent Information

E13 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F97 Word in reg. 48 heading omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(a)**

F98 Words in reg. 48(1) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(b)(i)**

F99 Words in reg. 48(1) omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(b)(ii)**

F100 Words in reg. 48(1) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(b)(iii)**

F101 Words in reg. 48(2) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(c)(i)**

F102 Words in reg. 48(2) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(c)(ii)**

F103 Words in reg. 48(4) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(d)**

F104 Words in reg. 48(5) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(e)(i)**

F105 Words in reg. 48(5) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(e)(ii)**

F106 Words in reg. 48(6) omitted (N.I.) (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(f)**

F107 Words in reg. 48(7) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(g)(i)**

F108 Words in reg. 48(7) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(g)(ii)**

F109 Words in reg. 48(8) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(h)(i)**

F110 Words in reg. 48(8) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 18(h)(ii)**

[F70Fees charged by approved bodies and conformity assessment bodies] E+W+S

49.—(1) **[**F71An approved body or CAB**]** may charge a fee in accordance with paragraphs (2), (3) and (4) for anything done in, or in connection with—

[F72(a) in the case of an approved body, performing the functions of an approved body or an importing Party under these Regulations or a mutual recognition agreement; and**]**

(b) in the case of **[**F73a CAB**]**, performing the functions of **[**F73a CAB**]** arising out of **[**F74a mutual recognition agreement**]** 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 **[**F75approved body or 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 **[**F76approved body**]**; and

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

(4) The **[**F77approved body or 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.

Extent Information

E6 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F70 Reg. 49 heading substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(9)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F71 Words in reg. 49(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(9)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F72 Reg. 49(1)(a) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(9)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F73 Words in reg. 49(1)(b) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(9)(d)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F74 Words in reg. 49(1)(b) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(9)(d)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F75 Words in reg. 49(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(9)(e)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F76 Words in reg. 49(3)(a) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(9)(e)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F77 Words in reg. 49(4) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(9)(f)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F111**Fees charged by UK notified bodies and conformity assessment bodies]** N.I.

49.—(1) A UK notified body or **[**F112CAB**]** 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 **[**F113the Medical Devices Directives or a UK mutual recognition agreement in respect of a conformity assessment procedure set out in the Medical Devices Directives or these Regulations as they apply in Great Britain**]**; and

(b) in the case of **[**F114a CAB**]**, performing the functions of **[**F114a CAB**]** arising out of **[**F115a UK mutual recognition agreement**]** 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 **[**F116CAB**]** 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 **[**F117CAB**]** 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.

Extent Information

E14 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F111 Reg. 49 heading substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 19(a)**

F112 Word in reg. 49(1) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 19(b)**

F113 Words in reg. 49(1)(a) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 19(c)**

F114 Words in reg. 49(1)(b) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 19(d)(i)**

F115 Words in reg. 49(1)(b) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 19(d)(ii)**

F116 Word in reg. 49(3) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 19(e)**

F117 Word in reg. 49(4) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 19(f)**

Products incorrectly marked with [F78an approved body] or conformity assessment body number E+W+S

50.—(1) No person shall—

(a) affix **[**F79an approved 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 **[**F79an approved 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 **[**F79an approved body**]** or conformity assessment body withdrawn.

(2) No person shall provide information comprising **[**F80an approved 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) **[**F81the approved 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 **[**F80an approved 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 **[**F82an approved body**]**; and

(b) the device bears the **[**F83approved body**]** number of that **[**F83approved body**]**.

(4) For the purposes of this regulation, **[**F84an approved 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.

Extent Information

E7 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F78 Words in reg. 50 heading substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(10)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F79 Words in reg. 50(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(10)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F80 Words in reg. 50(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(10)(c)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F81 Words in reg. 50(2)(b) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(10)(c)(Ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F82 Words in reg. 50(3)(a) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(10)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F83 Words in reg. 50(3)(b) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(10)(e)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F84 Words in reg. 50(4) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(10)(f)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

Products incorrectly marked with a notified body or conformity assessment body number N.I.

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.

Extent Information

E15 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Products incorrectly marked with a [F85UK marking] E+W+S

51.—(1) No person shall—

(a) affix the **[**F86UK 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 **[**F86UK marking**]** for a medical device if that product is not a medical device.

(2) No person shall provide information comprising a **[**[F86]UK 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.

Extent Information

E8 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F85 Words in reg. 51 heading substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(11)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

F86 Words in reg. 51 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **7(11)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **47**); 2020 c. 1, **Sch. 5 para. 1(1)**

Products incorrectly marked with a CE marking N.I.

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.

Extent Information

E16 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Status:
Point in time view as at 31/12/2020.

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 03 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.