STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART V

[F1 Notified Bodies][F1 Approved Bodies], Conformity Assessment Bodies and Marking of Products

Designation etc. of [F2approved bodies] E+W+S

45.—(1) The Secretary of State may designate for the purposes of [F3these Regulations] any corporate or other body as a body which is to carry out any of the tasks of [F4an approved body], and, if he so designates a body (referred to in these Regulations as [F5an "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 [F6an 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 [F7Part III], it is a body in respect of which the criteria for the designation of [F8approved bodies set out in Annex 8 of Directive 90/385][F9, 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 [F10Part II], it is a body in respect of which the criteria for the designation of [F11approved bodies set out in Annex XI of Directive 93/42][F12, read with [F13Regulation (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 [F14Part IV], it is a body in respect of which the criteria for the designation of [F15approved 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 [F16a 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 [F17an 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, [F18both 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 **[**F19a 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 **[**F20the approved body's request**]**, the Secretary of State shall give to the **[**F21approved 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, **[**F22both 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 **[**F23a 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 **[**F24an 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, **[**F25both 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 **[**F26a 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

F2 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)**

F3 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)**

F4 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)**

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)(iii)** (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(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)**

F7 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)**

F8 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)**

F9 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)**

F10 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)**

F11 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)**

F12 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)**

F13 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)**

F14 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)**

F15 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)**

F16 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)**

F17 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)**

F18 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)**

F19 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)**

F20 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)**

F21 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)**

F22 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)**

F23 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)**

F24 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)**

F25 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)**

F26 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 **[**[F27]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 **[**[F28], 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 **[**[F29], read with **[**[F30]Regulation (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, **[**[F31]both 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, **[**F32both 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, **[**F33both 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

E2 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

F27 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**

F28 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)**

F29 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)**

F30 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)**

F31 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)**

F32 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)**

F33 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)**