STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART VII

General, Enforcement and Miscellaneous

Interpretation of Part VII

59. In this Part[F1]...—

"registrable device" means a device in respect of which, in accordance with the Medical Devices Directives, registration is required with the competent authorities of a Member State or (where appropriate) a State which is a Party to an Association Agreement;

"relevant device" means a device that is a "relevant device" for the purposes of Part II, III or IV.

Textual Amendments

F1 Words in reg. 59 omitted (1.9.2003) by virtue of The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **17**

[F2Status of UK responsible person] E+W+S

60.—F3(1) . . . . . .

F3(2) . . . . . .

[F4(3) A UK responsible person—

(a) may be proceeded against as a person placing the device on the market for the purposes of these regulations;

(b) in relation to the supply of the device to a person within the United Kingdom after it has been placed on the market, may be proceeded against as a person supplying the device after it has been placed on the market.]

(4) If a person claims or purports to act as [F5a UK responsible person], the Secretary of State may, for the purposes of enabling the Secretary of State to exercise his functions under these Regulations, require that person to furnish the Secretary of State with sufficient [F6evidence that he is [F7a UK responsible person]].

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 Reg. 60 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), **9(3)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F3 Reg. 60(1)(2) 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), **9(3)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F4 Reg. 60(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), **9(3)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F5 Words in reg. 60(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), **9(3)(d)(i)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 8** and S.I. 2020/1478, regs. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**

F6 Words in reg. 60(4) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **17(b)**

F7 Words in reg. 60(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), **9(3)(d)(ii)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 8** and S.I. 2020/1478, regs. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**

Designation etc. of authorised representatives N.I.

60.—(1) Where these Regulations place any obligation[F36]... on a manufacturer of a device or his authorised representative, and the manufacturer does not have a registered place of business **[**[F37]in a relevant state**]**, no person shall—

(a) place that device on the market; or

(b) supply that device in circumstances where it has been placed on the market,

unless the manufacturer of the device has designated **[**[F38]a single authorised representative**]** to perform that obligation, but once the manufacturer has designated **[**[F38]a single authorised representative**]** to perform that obligation, that obligation shall be performed by the authorised representative (although in all other cases it shall be performed by the manufacturer).

(2) If the manufacturer of a registrable device does not have a registered place of business **[**[F39]in a relevant state**]**, no person shall place that device on the market or supply that device in circumstances where it has been placed on the market unless its manufacturer has designated **[**[F38]a single authorised representative**]** as—

(a) the person responsible for marketing the device **[**[F40]in a relevant state**]**; and

(b) the person responsible for registering in respect of that device with—

(i) the Secretary of State in accordance with regulation 19 or, as the case may be, 44, or

(ii) the competent authorities of another Member State or (where appropriate) a State which is a Party to an Association Agreement.

(3) Where a manufacturer of a registrable device, or of a relevant device that is not registrable, has designated **[**[F38]a single authorised representative**]** as the person responsible for marketing the device within **[**[F41]a relevant state**]**, that authorised representative—

(a) may be proceeded against as a person placing the device on the market for the purposes of these Regulations;

(b) in relation to any supply of the device to a person within **[**[F42]Northern Ireland**]** after it has been placed on the market, may be proceeded against as a person supplying the device

after it has been placed on the market, unless that supply is due to an act of another person established in **[**[F43]a relevant state**]**.

(4) If a person claims or purports to act as an authorised representative of a manufacturer of a device, the Secretary of State may, for the purposes of enabling the Secretary of State to exercise his functions under these Regulations, require that person to furnish the Secretary of State with sufficient **[**[F44]evidence that he is the single authorised representative of the manufacturer**]**.

Extent Information

E6 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

F36 Words in reg. 60(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. 23(a)(i)**

F37 Words in reg. 60(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. 23(a)(ii)**

F38 Words in reg. 60(1)(2)(3) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **17(a)**

F39 Words in reg. 60(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. 23(b)(i)**

F40 Words in reg. 60(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. 23(b)(ii)**

F41 Words in reg. 60(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. 23(c)(i)**

F42 Words in reg. 60(3)(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. 23(c)(ii)(aa)**

F43 Words in reg. 60(3)(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. 23(c)(ii)(bb)**

F44 Words in reg. 60(4) substituted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **17(b)**

Enforcement etc. E+W+S

61.—(1) Notwithstanding that they are made partly in exercise of powers other than those conferred by section 11 of the 1987 Act, these Regulations shall be regarded for all purposes relating to enforcement (whether by criminal proceedings, notices or otherwise) [F8]... as safety regulations as defined in that Act [M1], and any provision of these Regulations made under those other powers shall be regarded for those purposes as a safety provision as defined in that Act [M2].

(2) Except as provided by paragraph (3), each weights and measures authority in Great Britain and each district council in Northern Ireland is relieved of its duty imposed by section 27(1) of the 1987 Act in so far as it is exercisable in relation to relevant devices or devices for performance evaluation, and that duty is transferred to the Secretary of State.

(3) Paragraph (2) does not relieve an authority or council of its duty in relation to devices which are consumer goods[F9]..., and accordingly but subject to paragraph (4), each weights and measures authority in Great Britain and each district council in Northern Ireland shall, concurrently with the Secretary of State, enforce these Regulations in relation to such devices.

(4) The powers of an enforcement authority to serve restriction notices under regulation 63 are only exercisable by the Secretary of State.

(5) Each authority and council referred to in paragraph (3) on whom a duty is imposed by section 27(1) of the 1987 Act to enforce the provisions of these Regulations shall give immediate notice to the Secretary of State of—

(a) any suspension notice served by it under section 14 of the 1987 Act in respect of a device to which paragraph (3) applies;

(b) any application made by it under section 16 of the 1987 Act for an order for forfeiture of any such device; and

(c) any other thing done by it in respect of such a device for the purposes of, or in connection with the operation of, sections 14 to 17 of the 1987 Act.

[[F10](6) In respect of an offence committed under section 12 of the 1987 Act relating to a contravention of these Regulations—

(a) a magistrates' court in England or Wales may try any information laid—

(i) if the offence was committed before 10th March 2007, within 12 months from the time when the offence is committed, or

(ii) if offence was committed on or after 10th March 2007, within three years from the time when the offence was committed or within one year from the discovery of the offence by the prosecutor, whichever is the earlier;

(b) a magistrates' court in Northern Ireland may hear and determine any complaint made—

(i) if the offence was committed before 10th March 2007, within 12 months from the time when the offence is committed, or

(ii) if the offence was committed on or after 10th March 2007, within three years from the time when the offence was committed or within one year from the discovery of the offence by the prosecutor, whichever is the earlier; and

(c) in Scotland, summary proceedings for the offence may be commenced—

(i) if the offence was committed before 10th March 2007, at any time within 12 months from the time when the offence is committed, or

(ii) if the offence was committed on or after 10th March 2007, within three years from the time when the offence was committed or within one year from the discovery of the offence by the prosecutor, whichever is the earlier.**]**

(7) The powers conferred by section 13 of the 1987 Act to serve prohibition notices and notices to warn are exercisable in relation to non—conforming devices as they are exercisable in relation to relevant goods which the Secretary of State considers are unsafe (as well as being exercisable in relation to goods considered unsafe by the Secretary of State), and in relation to non-conforming devices, Schedule 2 to the 1987 Act shall have effect as if references to goods being unsafe or safe were references to relevant devices being or not being non-conforming devices.

[[F11](7A) In paragraph (3), "consumer goods" means any goods which are ordinarily intended for private use or consumption.**]**

(8) In paragraph (7), "non-conforming devices" means—

(a) relevant devices which, whether or not the Secretary of State considers them unsafe, are devices with or that require a **[**[F12]UK marking**]** which he considers to be devices—

(i) which do not conform as respects a relevant essential requirement **[**F13, a general safety and performance requirement**][**F14or a requirement of Regulation (EU) No 722/2012 (if applicable)**]**; or

(ii) to which a **[**F12UK marking**]** has or should have been applied following a conformity assessment procedure F15..., and—

(aa) the manufacturer or **[**F16their UK responsible person**]** has failed to comply with his obligations under that procedure, or

(bb) they do not conform to the design or type described in any certificate granted as a result of that procedure; or

(b) devices for performance evaluation which, whether or not the Secretary of State considers them unsafe, are devices in respect of which there is a failure to comply with these Regulations.

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

F8 Words in reg. 61(1) revoked (20.6.2003) by The Enterprise Act 2002 (Part 9 Restrictions on Disclosure of Information) (Amendment and Specification) Order 2003 (S.I. 2003/1400), art. 1, **Sch. 5**

F9 Words in reg. 61(3) omitted (22.11.2005) by virtue of The Medical Devices (Amendment) Regulations 2005 (S.I. 2005/2909), regs. 1, **2(a)**

F10 Reg. 61(6) substituted (10.3.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(a), **6**

F11 Reg. 61(7A) inserted (22.11.2005) by The Medical Devices (Amendment) Regulations 2005 (S.I. 2005/2909), regs. 1, **2(b)**

F12 Words in reg. 61 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **9(4)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **51**); 2020 c. 1, **Sch. 5 para. 1(1)**

F13 Words in reg. 61(8)(a)(i) inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **9(4)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **51**); 2020 c. 1, **Sch. 5 para. 1(1)**

F14 Words in reg. 61(8)(a)(i) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **17**

F15 Words in reg. 61(8)(a)(ii) 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), **9(4)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **51**); 2020 c. 1, **Sch. 5 para. 1(1)**

F16 Words in reg. 61(8)(a)(ii)(aa) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **9(4)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **51**); 2020 c. 1, **Sch. 5 para. 1(1)**

Marginal Citations

M1 *See* section s 11(1) and 45(1) of that Act.

M2 *See* section 45(1) of that Act.

Enforcement etc. N.I.

61.—(1) Notwithstanding that they are made partly in exercise of powers other than those conferred by section 11 of the 1987 Act, these Regulations shall be regarded for all purposes relating

to enforcement (whether by criminal proceedings, notices or otherwise) [F45]... as safety regulations as defined in that Act [F46], and any provision of these Regulations made under those other powers shall be regarded for those purposes as a safety provision as defined in that Act [M10].

[[F47](1A) Paragraph (1) applies in relation to regulations 10A, 24A and 36A (UK(NI) indication) as it does in relation to any other provision of these Regulations to which it applies.**]**

(2) Except as provided by paragraph (3), [F48]... each district council in Northern Ireland is relieved of its duty imposed by section 27(1) of the 1987 Act in so far as it is exercisable in relation to relevant devices or devices for performance evaluation, and that duty is transferred to the Secretary of State.

(3) Paragraph (2) does not relieve an authority or council of its duty in relation to devices which are consumer goods[F49]..., and accordingly but subject to paragraph (4), [F50]... each district council in Northern Ireland shall, concurrently with the Secretary of State, enforce these Regulations in relation to such devices.

(4) The powers of an enforcement authority to serve restriction notices under regulation 63 are only exercisable by the Secretary of State.

(5) Each [F51]... council referred to in paragraph (3) on whom a duty is imposed by section 27(1) of the 1987 Act to enforce the provisions of these Regulations shall give immediate notice to the Secretary of State of—

(a) any suspension notice served by it under section 14 of the 1987 Act in respect of a device to which paragraph (3) applies;

(b) any application made by it under section 16 of the 1987 Act for an order for forfeiture of any such device; and

(c) any other thing done by it in respect of such a device for the purposes of, or in connection with the operation of, sections 14 to 17 of the 1987 Act.

[[F52](6) In respect of an offence committed under section 12 of the 1987 Act relating to a contravention of these Regulations—

[F53](a) . . . . . .

(b) a magistrates' court in Northern Ireland may hear and determine any complaint made—

(i) if the offence was committed before 10th March 2007, within 12 months from the time when the offence is committed, or

(ii) if the offence was committed on or after 10th March 2007, within three years from the time when the offence was committed or within one year from the discovery of the offence by the prosecutor, whichever is the earlier; and

[F54](c) . . . . . .**]**

(7) The powers conferred by section 13 of the 1987 Act to serve prohibition notices and notices to warn are exercisable in relation to non—conforming devices as they are exercisable in relation to relevant goods which the Secretary of State considers are unsafe (as well as being exercisable in relation to goods considered unsafe by the Secretary of State), and in relation to non-conforming devices, Schedule 2 to the 1987 Act shall have effect as if references to goods being unsafe or safe were references to relevant devices being or not being non-conforming devices.

[[F55](7A) In paragraph (3), "consumer goods" means any goods which are ordinarily intended for private use or consumption.**]**

(8) In paragraph (7), "non-conforming devices" means—

(a) relevant devices which, whether or not the Secretary of State considers them unsafe, are devices with or that require a CE marking which he considers to be devices—

(i) which do not conform as respects a relevant essential requirement **[**[F56]or a requirement of Regulation (EU) No 722/2012 (if applicable)**]**; or

(ii) to which a CE marking has or should have been applied following a conformity assessment procedure set out in the Medical Devices Directives, and—

(aa) the manufacturer or his authorised representative has failed to comply with his obligations under that procedure, or

(bb) they do not conform to the design or type described in any certificate granted as a result of that procedure; or

(b) devices for performance evaluation which, whether or not the Secretary of State considers them unsafe, are devices in respect of which there is a failure to comply with these Regulations.

Extent Information

E7 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

F45 Words in reg. 61(1) revoked (20.6.2003) by The Enterprise Act 2002 (Part 9 Restrictions on Disclosure of Information) (Amendment and Specification) Order 2003 (S.I. 2003/1400), art. 1, **Sch. 5**

F46 *See* section s 11(1) and 45(1) of that Act.

F47 Reg. 61(1A) 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. 24(a)**

F48 Words in reg. 61(2) 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. 24(b)**

F49 Words in reg. 61(3) omitted (22.11.2005) by virtue of The Medical Devices (Amendment) Regulations 2005 (S.I. 2005/2909), regs. 1, **2(a)**

F50 Words in reg. 61(3) 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. 24(c)**

F51 Words in reg. 61(5) 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. 24(d)**

F52 Reg. 61(6) substituted (10.3.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(a), **6**

F53 Reg. 61(6)(a) 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. 24(e)**

F54 Reg. 61(6)(c) 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. 24(e)**

F55 Reg. 61(7A) inserted (22.11.2005) by The Medical Devices (Amendment) Regulations 2005 (S.I. 2005/2909), regs. 1, **2(b)**

F56 Words in reg. 61(8)(a)(i) inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **17**

Marginal Citations

M10 *See* section 45(1) of that Act.

Compliance notices E+W+S

62.—(1) Except in the case of a device which in the opinion of an enforcement authority is likely to compromise the health or safety of any person, where an enforcement authority has reasonable grounds for suspecting that a relevant device or a device for performance evaluation **[**[F17]or study**]** is a device in respect of which there is a failure to comply with these Regulations, that authority may serve upon **[**[F18]any person**]** a notice—

(a) specifying the description of the device to which the notice relates;

(b) stating that the enforcement authority suspects the device is a device in respect of which there is failure to comply with these Regulations and the reasons for that suspicion;

(c) specifying the relevant provision of these Regulations [F19]...;

(d) requiring the person on whom the notice is served—

(i) to secure that any device to which the notice relates conforms as regards the specified provision within such period as may be specified in the notice, or

(ii) to provide evidence within that period to the satisfaction of the enforcement authority that all the provisions of these Regulations have been complied with in so far as they relate to that device; and

(e) warning the person on whom the notice is served that unless the requirements of sub—paragraph (d) are met, further action may be taken under these Regulations or the 1987 Act in respect of that device or any device of the same type supplied by that person.

(2) Where an enforcement authority serves a notice referred to in paragraph (1), section 14, 16 or 17 of the 1987 Act shall not be applied as respects any device to which the notice relates until the period referred to in paragraph (1)(d) has expired and unless, in relation to the alleged failure to comply with these Regulations, at the expiry of that period the person on whom the notice was served has failed to comply with its requirements.

(3) The notice referred to in paragraph (1) may include directions as to the measures to be taken by the person on whom the notice is served to secure compliance with the provisions of these Regulations, including different ways of securing compliance, and any such directions are requirements of the notice for the purposes of paragraph (2).

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

F17 Words in reg. 62(1) inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **9(5)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F18 Words in reg. 62(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), **9(5)(ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F19 Words in reg. 62(1)(c) 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), **9(5)(iii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **52**); 2020 c. 1, **Sch. 5 para. 1(1)**

Compliance notices N.I.

62.—(1) Except in the case of a device which in the opinion of an enforcement authority is likely to compromise the health or safety of any person, where an enforcement authority has reasonable grounds for suspecting that a relevant device or a device for performance evaluation is a device in respect of which there is a failure to comply with these Regulations, that authority may serve upon the manufacturer or his authorised representative a notice—

(a) specifying the description of the device to which the notice relates;

(b) stating that the enforcement authority suspects the device is a device in respect of which there is failure to comply with these Regulations and the reasons for that suspicion;

(c) specifying the relevant provision of these Regulations and, where applicable, any relevant provision of the Medical Devices Directives;

(d) requiring the person on whom the notice is served—

(i) to secure that any device to which the notice relates conforms as regards the specified provision within such period as may be specified in the notice, or

(ii) to provide evidence within that period to the satisfaction of the enforcement authority that all the provisions of these Regulations have been complied with in so far as they relate to that device; and

(e) warning the person on whom the notice is served that unless the requirements of sub—paragraph (d) are met, further action may be taken under these Regulations or the 1987 Act in respect of that device or any device of the same type supplied by that person.

(2) Where an enforcement authority serves a notice referred to in paragraph (1), section 14, 16 or 17 of the 1987 Act shall not be applied as respects any device to which the notice relates until the period referred to in paragraph (1)(d) has expired and unless, in relation to the alleged failure to comply with these Regulations, at the expiry of that period the person on whom the notice was served has failed to comply with its requirements.

(3) The notice referred to in paragraph (1) may include directions as to the measures to be taken by the person on whom the notice is served to secure compliance with the provisions of these Regulations, including different ways of securing compliance, and any such directions are requirements of the notice for the purposes of paragraph (2).

Extent Information

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

Restriction notices

63.—(1) [F20]... Where an enforcement authority is of the opinion that it is necessary to restrict the availability of—

(a) a particular medical device, a particular accessory to such a device or a particular device for performance evaluation **[**[F21]or study**]**; or

(b) medical devices, accessories to such devices or devices for performance evaluation **[**[F22]or study**]** of a particular class or description,

in order to protect the health or safety of any individual or of individuals of any class or description, they may serve on any person a notice ("a restriction notice") including such directions restricting the availability of that device or those devices as appear to them to be necessary in order to protect the health or safety of that individual or individuals of that class or description.

F23(2) . . . . . .

(3) The enforcement authority responsible for serving a restriction notice may, in appropriate circumstances, withdraw the notice.

(4) A direction in a restriction notice that has not been withdrawn by an enforcement authority or set aside by an order of a court **[**F24or a sheriff**]** is a safety provision for the purposes of sections 14 to 17 of the 1987 Act.

(5) Where, in the course of or as a result of enforcement action in relation to a suspected contravention of a direction in a restriction notice, an application has been made to a magistrates' court **[**F25or a sheriff**]**—

(a) under section 15 of the 1987 Act (appeals against suspension notices), the court **[**F26or the sheriff**]** may make an order setting aside the restriction notice as well as any suspension notice served in respect of the suspected contravention of the direction;

(b) under section 16 or 17 of the 1987 Act (which relate to forfeiture of goods), the court **[**F27or the sheriff**]** may make an order setting aside the restriction notice,

if the court **[**F28or the sheriff**]** is satisfied that the restriction notice should not have been served or should be withdrawn.

(6) Any person aggrieved by an order made under paragraph (5), or by a decision not to make such an order, may appeal against that order or decision, and that appeal shall be treated in the same way as any other appeal that has been or could be made against any other decision or order of the court in the proceedings under section 15, 16 or 17 of the 1987 Act which led to the decision or order relating to the restriction notice being made.

Textual Amendments

F20 Words in reg. 63(1) omitted (21.3.2010) by virtue of The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **18(a)**

F21 Words in reg. 63(1)(a) inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **9(6)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F22 Words in reg. 63(1)(b) inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **9(6)(ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F23 Reg. 63(2) omitted (21.3.2010) by virtue of The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **18(b)**

F24 Words in reg. 63(4) 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. 25(a)**

F25 Words in reg. 63(5) 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. 25(b)(i)**

F26 Words in reg. 63(5)(a) 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. 25(b)(ii)**

F27 Words in reg. 63(5)(b) 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. 25(b)(iii)**

F28 Words in reg. 63(5) 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. 25(b)(iv)**

Notification of decisions etc. E+W+S

64.—(1) Any decision taken by a UK notified body, the Secretary of State or any other enforcement authority pursuant to these Regulations to withdraw a device from the market, or to prevent or restrict a device being placed on the market, put into service or made available, shall be notified without delay to the person responsible for marketing the device, placing it on the market, putting it into service or making it available, and that person shall be informed—

(a) of the grounds on which the decision is based;

(b) of the legal remedies available to that person and of any time limits which apply to their exercise; and

(c) if the applicant was not entitled under the 1987 Act to make representations in respect of the decision, that the decision maker will, on request, review the decision and in the course of so doing will give **[**F29the applicant or the applicant's UK responsible person**]** an opportunity to make representations in respect of the decision.

(2) Except in cases where urgent action is justified (in particular by public health requirements), if **[**F30an approved body**]**, the Secretary of State or any other enforcement authority is considering making a decision referred to in paragraph (1), they or he shall give the manufacturer or **[**F31their UK responsible person**]** an opportunity to make representations to them or him before the decision is taken.

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

F29 Words in reg. 64(1)(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), **9(6A)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **53**); 2020 c. 1, **Sch. 5 para. 1(1)**

F30 Words in reg. 64(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), **9(6A)(b)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **53**); 2020 c. 1, **Sch. 5 para. 1(1)**

F31 Words in reg. 64(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), **9(6A)(b)(Ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **53**); 2020 c. 1, **Sch. 5 para. 1(1)**

Notification of decisions etc. N.I.

64.—(1) Any decision taken by a UK notified body, the Secretary of State or any other enforcement authority pursuant to these Regulations to withdraw a device from the market, or to prevent or restrict a device being placed on the market, put into service or made available, shall be notified without delay to the person responsible for marketing the device, placing it on the market, putting it into service or making it available, and that person shall be informed—

(a) of the grounds on which the decision is based;

(b) of the legal remedies available to that person and of any time limits which apply to their exercise; and

(c) if the applicant was not entitled under the 1987 Act to make representations in respect of the decision, that the decision maker will, on request, review the decision and in the course of so doing will give him or his authorised representative an opportunity to make representations in respect of the decision.

(2) Except in cases where urgent action is justified (in particular by public health requirements), if a UK notified body, the Secretary of State or any other enforcement authority is considering making a decision referred to in paragraph (1), they or he shall give the manufacturer or his authorised representative an opportunity to make representations to them or him before the decision is taken.

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

[F32 Centralised systems of records etc.

65. The Secretary of State shall perform, as respects **[**F33Northern Ireland**]**, the functions of the Member State under article 8 of Directive 90/385, article 10 of Directive 93/42 and article 11(1) to (3) of Directive 98/79.**]**

Textual Amendments

F32 Reg. 65 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), **9(7)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F33 Words in reg. 65 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. 26**

Revocations

66. The following provisions are hereby revoked—

(a) the Active Implantable Medical Devices Regulations 1992 M3;

(b) the Medical Devices Regulations 1994 M4;

(c) the Active Implantable Medical Devices (Amendment and Transitional Provisions) Regulations 1995 M5;

(d) the Medical Devices Fees Regulations 1995 M6;

(e) the Medical Devices Fees (Amendment) Regulations 1997 M7;

(f) the*In Vitro* Diagnostic Medical Devices Regulations 2000 M8; and

(g) regulations 6 and 13 of the Medicines (Codification Amendments Etc.) Regulations 2002 M9.

Marginal Citations

M3 S.I. 1992/3146.
M4 S.I. 1994/3017.
M5 S.I. 1995/1671.
M6 S.I. 1995/2487.
M7 S.I. 1997/694.
M8 S.I. 2000/1315.
M9 S.I. 2002/236.

[F34Review E+W+S

67. Before the end of 31st December **[**F35**]**2025**]**, the Secretary of State must—

(a) carry out a review of these Regulations;

(b) set out the conclusions of the review in a report; and

(c) publish the report.**]**

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

F34 Reg. 67 inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **18**

F35 Word in reg. 67 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **9(8)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

[F57Review N.I.

67. Before the end of 31st December 2019, the Secretary of State must—

(a) carry out a review of these Regulations;

(b) set out the conclusions of the review in a report; and

(c) publish the report.**]**

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

Textual Amendments

F57 Reg. 67 inserted (21.10.2013) by The Medical Devices (Amendment) Regulations 2013 (S.I. 2013/2327), regs. 1(2), **18**

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

Changes to legislation:
The Medical Devices Regulations 2002, PART VII is up to date with all changes known to be in force on or before 18 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.