

## STATUTORY INSTRUMENTS

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# 2002 No. 618

## The Medical Devices Regulations 2002

### PART VII

#### *General, Enforcement and Miscellaneous*

#### **Enforcement etc.** **E+W+S**

<sup>F1</sup>61.—(1A) It is the duty of the Secretary of State to enforce these regulations in relation to relevant devices and devices for performance evaluation.

(1B) It is the duty of each weights and measures authority in Great Britain and each district council in Northern Ireland to enforce these regulations within its area (concurrently with the Secretary of State) in relation to relevant devices that are ordinarily intended for private use or consumption.

(1C) Nothing in this regulation authorises a weights and measures authority to bring proceedings in Scotland for an offence.]

#### **Textual Amendments**

**F1** Reg. 61(1A)-(1C) substituted for reg. 61(1)-(8) (26.5.2021) by [Medicines and Medical Devices Act 2021 \(c. 3\), ss. 41\(6\), 50\(3\)](#) (with s. 41(8)); S.I. 2021/610, reg. 2(c) (with reg. 3)

#### **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) <sup>F2</sup>... as safety regulations as defined in that Act <sup>F3</sup>, 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 <sup>M1</sup>.

<sup>F4</sup>(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), <sup>F5</sup>... 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 <sup>F6</sup>..., and accordingly but subject to paragraph (4), <sup>F7</sup>... 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.

*Status: There are multiple versions of this provision on screen. These apply to different geographical extents. Skip to: E+W+S - England, Wales and Scotland extent N.I. - Northern Ireland extent*

*Changes to legislation: The Medical Devices Regulations 2002, Section 61 is up to date with all changes known to be in force on or before 20 May 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. (See end of Document for details) View outstanding changes*

(5) Each <sup>F8</sup>... 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.

[<sup>F9</sup>(6) In respect of an offence committed under section 12 of the 1987 Act relating to a contravention of these Regulations—

- <sup>F10</sup>(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

<sup>F11</sup>(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.

[<sup>F12</sup>(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 [<sup>F13</sup>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**

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

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### Textual Amendments

- F2** 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**
- F3** See section s 11(1) and 45(1) of that Act.
- F4** 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)**
- F5** 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)**
- F6** 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)**
- F7** 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)**
- F8** 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)**
- F9** Reg. 61(6) substituted (10.3.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(a), **6**
- F10** 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)**
- F11** 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)**
- F12** Reg. 61(7A) inserted (22.11.2005) by The Medical Devices (Amendment) Regulations 2005 (S.I. 2005/2909), regs. 1, **2(b)**
- F13** 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

- M1** See section 45(1) of that Act.

**Status:**

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**Skip to:**

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- N.I. - Northern Ireland extent

**Changes to legislation:**

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**Changes and effects yet to be applied to :**

- reg. 61(8)(a)(i) words inserted by [S.I. 2019/791 reg. 9\(4\)\(a\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Reg. 9(4) substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 51)
- reg. 61(8)(a)(ii) words omitted by [S.I. 2019/791 reg. 9\(4\)\(a\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 9(4) substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 51)
- reg. 61(8)(b) words inserted by [S.I. 2019/791 reg. 9\(4\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Reg. 9(4) substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 51)

**Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:**

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Pt. 8 inserted by [S.I. 2019/791 reg. 10](#) (This amendment not applied to legislation.gov.uk. Reg. 10 omitted immediately before IP completion day by virtue of S.I. 2020/1478, regs. 1(3), Sch. 2 para. 54)
- Pt. 9 inserted by [S.I. 2019/791 reg. 11](#) (This amendment not applied to legislation.gov.uk. Reg. 11 omitted immediately before IP completion day by virtue of S.I. 2020/1478, regs. 1(3), Sch. 2 para. 55)
- Sch. 3 inserted by [2021 c. 3 Sch. 3 para. 2](#)
- Sch. 19 para. 5 words substituted by S.I. 2019/791, reg. 12 (as amended) by [S.I. 2019/1385 Sch. 2 para. 11\(2\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- Sch. 19 para. 5 words substituted by S.I. 2019/791, reg. 12 (as amended) by [S.I. 2019/1385 Sch. 2 para. 11\(2\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- Sch. 24 para. 1(7) heading words omitted by virtue of S.I. 2019/791, reg. 12 (as amended) by [S.I. 2019/1385 Sch. 2 para. 11\(3\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- Sch. 24 para. 1(7) words omitted by virtue of S.I. 2019/791, reg. 12 (as amended) by [S.I. 2019/1385 Sch. 2 para. 11\(3\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 4D(10)(b) substituted by S.I. 2019/791, reg. 3(7) (as amended) by [S.I. 2019/1385 Sch. 2 para. 2\(3\)\(a\)](#) (This amendment not applied to legislation.gov.uk.

- Sch. 2 para. 2(3) omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(a)(ii)
- reg. 4E(7) words substituted by S.I. 2019/791, reg. 3(7) (as amended) by [S.I. 2019/1385 Sch. 2 para. 2\(3\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 2(3) omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(a)(ii))
  - reg. 6(d) inserted by [S.I. 2019/791 reg. 4\(2\)](#) (This amendment not applied to legislation.gov.uk. Reg. 4(2) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 10)
  - reg. 33(1)(c) inserted by [S.I. 2019/791 reg. 6\(2\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Reg. 6(2) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 35)
  - reg. 33(2)(c) inserted by [S.I. 2019/791 reg. 6\(2\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Reg. 6(2) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 35)
  - reg. 60A excluded by [2021 c. 3 Sch. 2 para. 4](#)
  - reg. 60A excluded by [2021 c. 3 Sch. 2 para. 5\(2\)](#)
  - reg. 60A-60C inserted by [2021 c. 3 Sch. 3 para. 1](#)
  - reg. 75(3) words inserted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(2\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
  - reg. 75(7) inserted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(2\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
  - reg. 93(4) inserted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(3\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
  - reg. 119(6) words inserted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(4\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
  - reg. 124(5) words substituted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(5\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
  - reg. 149(5)(e) words substituted by S.I. 2019/791, reg. 11 (as amended) by [S.I. 2019/1385 Sch. 2 para. 10\(2\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
  - reg. 158(1) substituted by S.I. 2019/791, reg. 11 (as amended) by [S.I. 2019/1385 Sch. 2 para. 10\(3\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
  - reg. 158(3) inserted by S.I. 2019/791, reg. 11 (as amended) by [S.I. 2019/1385 Sch. 2 para. 10\(3\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))