

STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART VII

General, Enforcement and Miscellaneous

[^{F1}Status of UK responsible person] **E+W+S**

60.—^{F2}(1)

^{F2}(2)

[^{F3}(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 [^{F4}a 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 [^{F5}evidence that he is [^{F6}a 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

- F1** 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)
- F2** 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)
- F3** 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)
- F4** 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)**
- F5** 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)**

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 60 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

F6 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^{F7}... on a manufacturer of a device or his authorised representative, and the manufacturer does not have a registered place of business [^{F8}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 [^{F9}a single authorised representative] to perform that obligation, but once the manufacturer has designated [^{F9}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 [^{F10}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 [^{F9}a single authorised representative] as—

- (a) the person responsible for marketing the device [^{F11}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 [^{F9}a single authorised representative] as the person responsible for marketing the device within [^{F12}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 [^{F13}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 [^{F14}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 [^{F15}evidence that he is the single authorised representative of the manufacturer].

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

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 60 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

Textual Amendments

- F7** 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)**
- F8** 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)**
- F9** 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)**
- F10** 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)**
- F11** 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)**
- F12** 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)**
- F13** 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)**
- F14** 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)**
- F15** 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)**

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 60 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.

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Changes and effects yet to be applied to :

- reg. 60(4) words substituted by [S.I. 2019/791 reg. 9\(3\)\(d\)](#) (This amendment not applied to [legislation.gov.uk](#). Reg. 9(3)(d) substituted immediately before IP completion day by [S.I. 2019/1385](#), reg. 1, Sch. 2 para. 8)

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))