

STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART IV

In Vitro Diagnostic Medical Devices

Exemptions from [^{F1}this Part] **E+W+S**

39.—(1) A relevant device being shown at a trade fair, exhibition, scientific gathering or technical gathering is not being placed on the market or put into service if—

- (a) the device is not used on any specimen taken from the participants; and
- (b) a visible sign clearly indicates that the device cannot be marketed or put into service until it complies with the requirements of ^{F2}... these Regulations.

(2) Regulations 34, 36 and 38 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a [^{F3}UK marking], where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

[^{F4}(3) Regulations 34 and 36 do not apply where the Secretary of State directs that a relevant device, or a class of relevant devices, which meets other requirements or standards or which is marked other than with a UK marking which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 34 and 36, may be placed on the market.

(4) In paragraph (3), the Secretary of State, in determining whether a standard or requirement or marking (“the other standard”) is equivalent to a standard or requirement imposed by regulations 34 and 36, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.]

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** Words in [reg. 39](#) heading substituted (28.7.2021) by [The Medical Devices \(Coronavirus Test Device Approvals\) \(Amendment\) Regulations 2021 \(S.I. 2021/910\)](#), regs. 1(1), [7](#)
- F2** Words in [reg. 39\(1\)\(b\)](#) 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), [6\(5\)\(a\)](#) (as amended by [S.I. 2020/1478](#), regs. 1(3), [Sch. 2 paras. 2, 40](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F3** Words in [reg. 39\(2\)](#) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [6\(5\)\(b\)](#) (as amended by [S.I. 2020/1478](#), regs. 1(3), [Sch. 2 paras. 2, 40](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

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 39 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

F4 Reg. 39(3)(4) inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **6(5)(c)** (as amended by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 paras. 2, 40); 2020 c. 1, **Sch. 5 para. 1(1)**

Exemptions from regulations 34, 36 and 38 **N.I.**

39.—(1) A relevant device being shown at a trade fair, exhibition, scientific gathering or technical gathering is not being placed on the market or put into service if—

- (a) the device is not used on any specimen taken from the participants; and
- (b) a visible sign clearly indicates that the device cannot be marketed or put into service until it complies with the requirements of Directive 98/79 or these Regulations.

(2) Regulations 34, 36 and 38 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a CE marking, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

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 39 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.

[View outstanding changes](#)

Changes and effects yet to be applied to :

- reg. 39(3)(4) inserted by [S.I. 2019/791 reg. 6\(5\)](#) (This amendment not applied to [legislation.gov.uk](#). Reg. 6(5) substituted immediately before IP completion day by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 para. 40)

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))