

## STATUTORY INSTRUMENTS

---

# 2002 No. 618

## The Medical Devices Regulations 2002

### PART II

#### *General Medical Devices*

#### **Procedures for affixing a [F1UK marking] to general medical devices** **E+W+S**

13.—(1) A relevant device falling within Class I may bear a [F2UK marking] only if its manufacturer or [F3their UK responsible person]—

- (a) fulfils the applicable obligations imposed by Annex VII;
- (b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of [F4this Part] which apply to it; and
- (c) ensures that the device meets the provisions of [F4this Part] which apply to it.

(2) A relevant device falling within Class IIa may bear a [F2UK marking] only if its manufacturer or [F3their UK responsible person]—

- (a) fulfils the applicable obligations imposed by—
  - (i) Annex II, excluding Section 4 of that Annex, or
  - (ii) Annex VII, together with Annex IV, V or VI;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of [F4this Part] which apply to it; and
- (c) ensures that the device meets the provisions of [F4this Part] which apply to it.

(3) A relevant device falling within Class IIb may bear a [F2UK marking] only if its manufacturer or [F3their UK responsible person]—

- (a) fulfils the applicable obligations imposed by—
  - (i) Annex II, excluding Section 4 of that Annex, or
  - (ii) Annex III, together with Annex IV, V or VI;
- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of [F4this Part] which apply to it; and
- (c) ensures that the device meets the provisions of [F4this Part] which apply to it.

(4) A relevant device falling within Class III may bear a [F2UK marking] only if its manufacturer or [F3their UK responsible person]—

- (a) fulfils the applicable obligations imposed by—
  - (i) Annex II, or
  - (ii) Annex III, together with Annex IV or V;

*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 13 is up to date with all changes known to be in force on or before 29 April 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*

- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of [<sup>F4</sup>this Part] which apply to it; <sup>F5</sup>...
- (c) ensures that the device meets the provisions of [<sup>F4</sup>this Part] which apply to it; [<sup>F6</sup>and]
- [<sup>F7</sup>(d) fulfils the obligations imposed by Regulation (EU) No 722/2012 (if applicable).]
- <sup>F8</sup>(5) .....
- <sup>F8</sup>(6) .....

**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. 13 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), [4\(7A\)\(a\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [17](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F2** Words in reg. 13 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(7A\)\(c\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [17](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F3** Words in reg. 13 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(7A\)\(d\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [17](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F4** Words in reg. 13 substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(7A\)\(b\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, [17](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F5** Word in reg. 13(4)(b) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), [4\(2\)\(a\)](#)
- F6** Word in reg. 13(4)(c) added (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), [4\(2\)\(b\)](#)
- F7** Reg. 13(4)(d) added (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), [4\(2\)\(c\)](#)
- F8** Reg. 13(5)(6) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), [4\(3\)](#)

**Procedures for affixing a CE marking to general medical devices** **N.I.**

**13.—(1)** A relevant device falling within Class I may bear a CE marking only if its manufacturer or his authorised representative—

- (a) fulfils the applicable obligations imposed by Annex VII;
- (b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 93/42 which apply to it; and
- (c) ensures that the device meets the provisions of Directive 93/42 which apply to it.

**(2)** A relevant device falling within Class IIa may bear a CE marking only if its manufacturer or his authorised representative—

- (a) fulfils the applicable obligations imposed by—
  - (i) Annex II, excluding Section 4 of that Annex, or
  - (ii) Annex VII, together with Annex IV, V or VI;

**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 13 is up to date with all changes known to be in force on or before 29 April 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

- (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and
  - (c) ensures that the device meets the provisions of Directive 93/42 which apply to it.
- (3) A relevant device falling within Class IIb may bear a CE marking only if its manufacturer or his authorised representative—
- (a) fulfils the applicable obligations imposed by—
    - (i) Annex II, excluding Section 4 of that Annex, or
    - (ii) Annex III, together with Annex IV, V or VI;
  - (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; and
  - (c) ensures that the device meets the provisions of Directive 93/42 which apply to it.
- (4) A relevant device falling within Class III may bear a CE marking only if its manufacturer or his authorised representative—
- (a) fulfils the applicable obligations imposed by—
    - (i) Annex II, or
    - (ii) Annex III, together with Annex IV or V;
  - (b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it; <sup>F9</sup>...
  - (c) ensures that the device meets the provisions of Directive 93/42 which apply to it; [<sup>F10</sup>and]
  - [<sup>F11</sup>(d) fulfils the obligations imposed by Regulation (EU) No 722/2012 (if applicable).]
- <sup>F12</sup>(5) .....
- <sup>F12</sup>(6) .....

**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**

- F9** Word in reg. 13(4)(b) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **4(2)(a)**
- F10** Word in reg. 13(4)(c) added (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **4(2)(b)**
- F11** Reg. 13(4)(d) added (21.10.2013) by [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **4(2)(c)**
- F12** Reg. 13(5)(6) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **4(3)**

**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 13 is up to date with all changes known to be in force on or before 29 April 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 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))