

STATUTORY INSTRUMENTS

**2002 No. 618**

**The Medical Devices Regulations 2002**

**PART II**

*General Medical Devices*

**[<sup>F1</sup>Approved bodies] and the conformity assessment procedures for general medical devices E+W+S**

**18.**—(1) [<sup>F2</sup>An approved body] which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

- (a) take account of the results of any assessment or verification operations which have been carried out <sup>F3</sup>... at an intermediate stage of manufacture of the device;
- (b) take account of any relevant information relating to the characteristics and performance of that device, <sup>F4</sup>...; and
- (c) lay down, by common accord with the manufacturer or his authorised representative, the time limits for completion of the assessment and verification operations referred to in Annex II to IV.

(2) Where [<sup>F5</sup>an approved body] takes a decision in accordance with [<sup>F6</sup>Annex II, III, V or VI,] they shall specify the period of validity of the decision, which initially shall be for a period of not more than five years.

(3) Where [<sup>F7</sup>an approved body] and a manufacturer or [<sup>F8</sup>the manufacturer's UK responsible person] have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or [<sup>F8</sup>the manufacturer's UK responsible person], extend the period of validity of the decision for further periods of up to five years, each such period commencing on the expiry of the previous period.

<sup>F9</sup>(4) .....

**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. 18 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(9)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **22**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F2** Words in reg. 18(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), **4(9)(b)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **22**); 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 18 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*

- F3** Words in reg. 18(1)(a) omitted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(9\)\(b\)\(ii\)](#) (as amended by [S.I. 2020/1478](#), reg. 1(3), [Sch. 2 paras. 2, 22](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F4** Words in reg. 18(1)(b) omitted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), [4\(9\)\(b\)\(iii\)](#) (as amended by [S.I. 2020/1478](#), reg. 1(3), [Sch. 2 paras. 2, 22](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F5** Words in reg. 18(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), [4\(9\)\(c\)](#) (as amended by [S.I. 2020/1478](#), reg. 1(3), [Sch. 2 paras. 2, 22](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F6** Words in reg. 18(2) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), [10](#)
- F7** Words in reg. 18(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), [4\(9\)\(d\)\(i\)](#) (as amended by [S.I. 2020/1478](#), reg. 1(3), [Sch. 2 paras. 2, 22](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F8** Words in reg. 18(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), [4\(9\)\(d\)\(ii\)](#) (as amended by [S.I. 2020/1478](#), reg. 1(3), [Sch. 2 paras. 2, 22](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F9** Reg. 18(4) 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), [4\(9\)\(e\)](#) (as amended by [S.I. 2020/1478](#), reg. 1(3), [Sch. 2 paras. 2, 22](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

## UK notified bodies and the conformity assessment procedures for general medical devices **N.I.**

**18.—(1)** A UK notified body which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

- (a) take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 93/42 at an intermediate stage of manufacture of the device;
- (b) take account of any relevant information relating to the characteristics and performance of that device, including in particular the results of any relevant tests and verification relating to that device already carried out under the laws or administrative provisions in force before 1st January 1995 in any <sup>[F10]</sup>EEA State]; and
- (c) lay down, by common accord with the manufacturer or his authorised representative, the time limits for completion of the assessment and verification operations referred to in Annex II to IV.

(2) Where a UK notified body takes a decision in accordance with <sup>[F11]</sup>Annex II, III, V or VI,] they shall specify the period of validity of the decision, which initially shall be for a period of not more than five years.

(3) Where a UK notified body and a manufacturer or his authorised representative have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or his authorised representative, extend the period of validity of the decision for further periods of up to five years, each such period commencing on the expiry of the previous period.

<sup>[F12]</sup>(4) Decisions taken by UK notified bodies before 1st September 2003 in accordance with Annex II in respect of breast implants may not be extended.]

**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 18 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](#)

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### 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

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### Textual Amendments

- F10** Words in [reg. 18\(1\)\(b\)](#) substituted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), [regs. 1\(2\)](#), **8**
- F11** Words in [reg. 18\(2\)](#) substituted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), [regs. 1\(1\)](#), **10**
- F12** [Reg. 18\(4\)](#) added (1.9.2003) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), [regs. 1\(1\)\(a\)](#), **8**

**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 18 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. 18 omitted by [S.I. 2019/791 reg. 4\(9\)](#) (This amendment not applied to [legislation.gov.uk](#). Reg. 4(9) substituted immediately before IP completion day by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 para. 22)

**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))