

STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART V

[^{F1}Notified Bodies][^{F1}Approved Bodies], Conformity Assessment Bodies and Marking of Products

[^{F2}Fees charged by approved bodies and conformity assessment bodies] E+W+S

49.—(1) [^{F3}An approved body or CAB] may charge a fee in accordance with paragraphs (2), (3) and (4) for anything done in, or in connection with—

- [^{F4}(a) in the case of an approved body, performing the functions of an approved body or an importing Party under these Regulations or a mutual recognition agreement; and]
- (b) in the case of [^{F5}a CAB], performing the functions of [^{F5}a CAB] arising out of [^{F6}a mutual recognition agreement] in respect of a conformity assessment procedure for a medical device.

(2) Except as provided for by paragraph (3), the fee charged in respect of anything done shall not exceed an amount which reasonably represents the cost incurred, or to be incurred, in doing it.

(3) Where the [^{F7}approved body or CAB] charging the fee is a body the activities of which are carried on for profit, the fee may include an amount representing a profit which is reasonable in the circumstances, having regard to—

- (a) the character and extent of the work done or to be done by the [^{F8}approved body]; and
- (b) the commercial rate normally charged in respect of profit for that work or similar work.

(4) The [^{F9}approved body or CAB] may require payment of the fee, or a reasonable estimate of the fee, in advance of carrying out the work in respect of which the fee is payable and as a condition of doing that work.

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

- F2** Reg. 49 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), [7\(9\)\(a\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F3** Words in reg. 49(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), [7\(9\)\(b\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 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 49 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. 49(1)(a) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(9)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F5** Words in reg. 49(1)(b) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(9)(d)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F6** Words in reg. 49(1)(b) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(9)(d)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F7** Words in reg. 49(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), **7(9)(e)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F8** Words in reg. 49(3)(a) substituted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **7(9)(e)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F9** Words in reg. 49(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), **7(9)(f)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**

[^{F10}Fees charged by UK notified bodies and conformity assessment bodies] N.I.

49.—(1) A UK notified body or [^{F11}CAB] may charge a fee in accordance with paragraphs (2), (3) and (4) for anything done in, or in connection with—

- (a) in the case of a UK notified body, performing the functions of a notified body or an importing Party under [^{F12}the Medical Devices Directives or a UK mutual recognition agreement in respect of a conformity assessment procedure set out in the Medical Devices Directives or these Regulations as they apply in Great Britain]; and
- (b) in the case of [^{F13}a CAB], performing the functions of [^{F13}a CAB] arising out of [^{F14}a UK mutual recognition agreement] in respect of a conformity assessment procedure for a medical device.

(2) Except as provided for by paragraph (3), the fee charged in respect of anything done shall not exceed an amount which reasonably represents the cost incurred, or to be incurred, in doing it.

(3) Where the UK notified body or [^{F15}CAB] charging the fee is a body the activities of which are carried on for profit, the fee may include an amount representing a profit which is reasonable in the circumstances, having regard to—

- (a) the character and extent of the work done or to be done by the notified body; and
- (b) the commercial rate normally charged in respect of profit for that work or similar work.

(4) The UK notified body or [^{F16}CAB] may require payment of the fee, or a reasonable estimate of the fee, in advance of carrying out the work in respect of which the fee is payable and as a condition of doing that work.

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

- F10** Reg. 49 heading 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. 19(a)**

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- F11** Word in reg. 49(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. 19(b)**
- F12** Words in reg. 49(1)(a) 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. 19(c)**
- F13** Words in reg. 49(1)(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. 19(d)(i)**
- F14** Words in reg. 49(1)(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. 19(d)(ii)**
- F15** Word in reg. 49(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. 19(e)**
- F16** Word in reg. 49(4) 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. 19(f)**

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 49 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. 49 heading word omitted by [S.I. 2019/791 reg. 7\(5\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Reg. 7 substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 47)
- reg. 49 word omitted by [S.I. 2019/791 reg. 7\(5\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Reg. 7 substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 47)
- reg. 49 heading word omitted by virtue of S.I. 2019/791, reg. 7(5)(a) (as substituted) by [S.I. 2019/1385 Sch. 2 para. 6\(3\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 6 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(b))
- reg. 49 words substituted by [S.I. 2019/791 reg. 7\(5\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Reg. 7 substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 47)
- reg. 49(1) words substituted by [S.I. 2019/791 reg. 7\(5\)\(c\)](#) (This amendment not applied to legislation.gov.uk. Reg. 7 substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 47)
- reg. 49(1) words substituted by S.I. 2019/791, reg. 7(5)(b)(i) (as substituted) by [S.I. 2019/1385 Sch. 2 para. 6\(3\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 6 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(b))
- reg. 49(1)(a) words substituted by S.I. 2019/791, reg. 7(5)(b)(ii) (as substituted) by [S.I. 2019/1385 Sch. 2 para. 6\(3\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 6 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(b))
- reg. 49(1)(b) words substituted by S.I. 2019/791, reg. 7(5)(b)(ii) (as substituted) by [S.I. 2019/1385 Sch. 2 para. 6\(3\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 6 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(b))
- reg. 49(1)(b) words substituted by S.I. 2019/791, reg. 7(5)(b)(iii) (as substituted) by [S.I. 2019/1385 Sch. 2 para. 6\(3\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 6 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(b))
- reg. 49(3) words substituted by S.I. 2019/791, reg. 7(5)(c) (as substituted) by [S.I. 2019/1385 Sch. 2 para. 6\(3\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 6 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(b))
- reg. 49(4) words substituted by S.I. 2019/791, reg. 7(5)(c) (as substituted) by [S.I. 2019/1385 Sch. 2 para. 6\(3\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 6 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(b))

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))