

## STATUTORY INSTRUMENTS

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# 2002 No. 618

## The Medical Devices Regulations 2002

### PART V

#### *[<sup>F1</sup>Notified Bodies][<sup>F1</sup>Approved Bodies], Conformity Assessment Bodies and Marking of Products*

#### **[<sup>F2</sup>General matters relating to approved bodies] E+W+S**

47.—(1) [<sup>F3</sup>An approved body] to which an application has been made by a manufacturer or [<sup>F4</sup>the manufacturer's UK responsible person] to perform the functions of [<sup>F5</sup>an approved body] under a conformity assessment procedure set out in [<sup>F6</sup>these Regulations] shall perform those functions, in accordance with the requirements of the procedure, if those functions are within the framework of tasks which the body is designated to carry out.

(2) Where a manufacturer or [<sup>F7</sup>the manufacturer's UK responsible person] has supplied information or data to [<sup>F8</sup>an approved body] in the course of a conformity assessment procedure, that body may, where duly justified, require the manufacturer to provide any additional information or data which it considers necessary for the purposes of that procedure.

(3) The information, data and correspondence that a manufacturer or [<sup>F9</sup>the manufacturer's UK responsible person supplies to an approved body] in the course of a conformity assessment procedure set out in [<sup>F10</sup>these Regulations] shall, <sup>F11</sup> ..., be in English <sup>F12</sup> ....

(4) [<sup>F13</sup>An approved body] shall, as respects a medical device which it has assessed <sup>F14</sup> ..., inform all [<sup>F15</sup>other approved bodies] and the Secretary of State of—

- (a) all certificates suspended or withdrawn; and
- (b) on request, all certificates issued or refused,

and shall also make available to them, on request, any or all additional relevant information.

(5) Where [<sup>F16</sup>an approved body] finds, as respects a medical device which it has assessed <sup>F14</sup> ..., that—

- (a) the applicable requirements of [<sup>F17</sup>these Regulations] have not been met or are no longer met; or
- (b) a certificate issued by it should not have been issued,

it may (having regard in particular to the principle of proportionality and the ability of the manufacturer to take appropriate corrective measures) suspend or withdraw the certificate issued in respect of that device or place restrictions on it, and in such cases, or in cases where the [<sup>F18</sup>approved body] is aware of circumstances in which the Secretary of State may need to take action pursuant to regulation 61, the [<sup>F18</sup>approved body] shall inform the Secretary of State thereof.

(6) The Secretary of State may request that [<sup>F19</sup>an approved body] supply to him any information and documents that the Secretary of State may, having regard to the terms of [<sup>F20</sup>a mutual recognition

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agreement], need to supply to a Party to <sup>F20</sup>a mutual recognition agreement], and the body shall supply to him any and all information or documents so requested.

(8) <sup>F21</sup>An approved body] shall provide conformity assessment bodies with all the information it is required to provide to those bodies under <sup>F22</sup>a mutual recognition agreement].

<sup>F23</sup>(9) .....

<sup>F23</sup>(10) .....

**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. 47 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(6)(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. 47(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(6)(b)(i)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F4** Words in reg. 47(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(6)(b)(ii)** (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. 47(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(6)(b)(iii)** (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. 47(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(6)(b)(iv)** (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. 47(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), **7(6)(c)(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. 47(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), **7(6)(c)(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. 47(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(6)(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)**
- F10** Words in reg. 47(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(6)(d)(iii)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F11** Words in reg. 47(3) 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), **7(6)(d)(iii)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F12** Words in reg. 47(3) 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), **7(6)(d)(iv)** (as amended by [S.I. 2020/1478](#), reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, **Sch. 5 para. 1(1)**
- F13** Words in reg. 47(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(6)(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)**
- F14** Words in reg. 47(4)(5) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **16**

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- F15** Words in reg. 47(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\(6\)\(e\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F16** Words in reg. 47(5) 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\(6\)\(f\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F17** Words in reg. 47(5)(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\(6\)\(f\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F18** Words in reg. 47(5) 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\(6\)\(f\)\(iii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F19** Words in reg. 47(6) 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\(6\)\(g\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F20** Words in reg. 47(6) 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\(6\)\(g\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F21** Words in reg. 47(8) 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\(6\)\(h\)\(i\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F22** Words in reg. 47(8) 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\(6\)\(h\)\(ii\)](#) (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, 47); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F23** Reg. 47(9)(10) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013](#) (S.I. 2013/2327), regs. 1(2), [15](#)

## General matters relating to UK notified bodies **N.I.**

47.—(1) A UK notified body to which an application has been made by a manufacturer or his authorised representative to perform the functions of a notified body under a conformity assessment procedure set out in the Medical Devices Directives shall perform those functions, in accordance with the requirements of the procedure, if those functions are within the framework of tasks which the body is designated to carry out.

(2) Where a manufacturer or his authorised representative has supplied information or data to a UK notified body in the course of a conformity assessment procedure, that body may, where duly justified, require the manufacturer to provide any additional information or data which it considers necessary for the purposes of that procedure.

(3) The information, data and correspondence that a manufacturer or his authorised representative supplies to a notified body in the course of a conformity assessment procedure set out in the Medical Devices Directives shall, if the notified body is within the United Kingdom, be in English or some other Community language acceptable to the notified body concerned.

(4) A UK notified body shall, as respects a medical device which it has assessed <sup>F24</sup>..., inform all other notified bodies and the Secretary of State of—

- (a) all certificates suspended or withdrawn; and
- (b) on request, all certificates issued or refused,

and shall also make available to them, on request, any or all additional relevant information.

(5) Where a UK notified body finds, as respects a medical device which it has assessed <sup>F24</sup>..., that—

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*Changes to legislation:* The Medical Devices Regulations 2002, Section 47 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

- (a) the applicable requirements of the Medical Devices Directives have not been met or are no longer met; or
- (b) a certificate issued by it should not have been issued,

it may (having regard in particular to the principle of proportionality and the ability of the manufacturer to take appropriate corrective measures) suspend or withdraw the certificate issued in respect of that device or place restrictions on it, and in such cases, or in cases where the notified body is aware of circumstances in which the Secretary of State may need to take action pursuant to regulation 61, the notified body shall inform the Secretary of State thereof.

(6) The Secretary of State may request that a UK notified body supply to him any information and documents that the Secretary of State may, having regard to the terms of the Mutual Recognition Agreements, need to supply to a Party to the Mutual Recognition Agreements, and the body shall supply to him any and all information or documents so requested.

(8) A UK notified body shall provide conformity assessment bodies with all the information it is required to provide to those bodies under the Mutual Recognition Agreements.

<sup>F25</sup>(9) .....

<sup>F25</sup>(10) .....

**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**

**F24** Words in [reg. 47\(4\)\(5\)](#) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **16**

**F25** [Reg. 47\(9\)\(10\)](#) omitted (21.10.2013) by virtue of [The Medical Devices \(Amendment\) Regulations 2013 \(S.I. 2013/2327\)](#), regs. 1(2), **15**

**Status:**

There are multiple versions of this provision on screen. These apply to different geographical extents.

**Skip to:**

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**Changes to legislation:**

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**Changes and effects yet to be applied to :**

- reg. 47(1) words substituted by [S.I. 2019/791 reg. 7\(3\)\(a\)\(i\)](#) (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. 47(1) words substituted by [S.I. 2019/791 reg. 7\(3\)\(a\)\(ii\)](#) (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. 47(3) words omitted by [S.I. 2019/791 reg. 7\(3\)\(b\)\(ii\)](#) (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. 47(3) words omitted by [S.I. 2019/791 reg. 7\(3\)\(b\)\(iii\)](#) (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. 47(3) words substituted by [S.I. 2019/791 reg. 7\(3\)\(b\)\(i\)](#) (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. 47(5) words substituted by [S.I. 2019/791 reg. 7\(3\)\(c\)](#) (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. 47(6) words substituted by [S.I. 2019/791 reg. 7\(3\)\(d\)](#) (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. 47(8) words substituted by [S.I. 2019/791 reg. 7\(3\)\(d\)](#) (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)

**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))