

STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART I

Introductory Provisions Relating to all Medical Devices

Scope of these Regulations **E+W+S**

3. These Regulations shall not apply to—
- (a) medicinal products governed by [^{F1}the Human Medicines Regulations 2012] (including medicinal products derived from human blood or human plasma ^{F2}...);
 - (b) human blood, human blood products, plasma or blood cells of human origin;
 - (c) devices that incorporate, at the time of placing on the market, human blood, blood products, plasma or blood cells of human origin, except for [^{F3}—
 - (i) stable derivatives devices,
 - (ii) active implantable medical devices and accessories to such devices, and
 - (iii) *in vitro* diagnostic medical devices and accessories to such devices,];]
 - (d) transplants or tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin [^{F4}, except for ^{F5}..., *in vitro* diagnostic medical devices and accessories to such devices][^{F6}save where medicinal products are incorporated as ancillary to the device];
 - [^{F7}(e) transplants or tissues or cells of animal origin, unless—
 - (i) a device is manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue, or
 - (ii) a product is ^{F8}... an *in vitro* diagnostic medical device, or an accessory to such a device;]]
 - (f) cosmetic products governed by [^{F9}Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30th November 2009 on cosmetic products;] or
 - ^{F10}(g)

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. 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), **3(5)(c)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 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 3 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

F2	Words in reg. 3(a) 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), 3(5)(c)(ii) (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
F3	Words in reg. 3(c) substituted (10.3.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(a), 3(a)
F4	Words in reg. 3(d) inserted (10.3.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(a), 3(b)
F5	Words in reg. 3(d) omitted (21.3.2010) by virtue of The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), 3(a)
F6	Words in reg. 3(d) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), 3(b)
F7	Reg. 3(e) substituted (10.3.2007) by The Medical Devices (Amendment) Regulations 2007 (S.I. 2007/400), regs. 1(a), 3(c)
F8	Words in reg. 3(e)(ii) omitted (21.3.2010) by virtue of The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), 3(c)
F9	Words in reg. 3(f) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), 3(5)(d) (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)
F10	Reg. 3(g) omitted (21.3.2010) by virtue of The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), 3(d)

Scope of these Regulations **N.I.**

- 3. These Regulations shall not apply to—
 - (a) medicinal products governed by Directive 2001/83 (including medicinal products derived from human blood or human plasma governed by Title X of Directive 2001/83);
 - (b) human blood, human blood products, plasma or blood cells of human origin;
 - (c) devices that incorporate, at the time of placing on the market, human blood, blood products, plasma or blood cells of human origin, except for ^{F11}—
 - (i) stable derivatives devices,
 - (ii) active implantable medical devices and accessories to such devices, and
 - (iii) *in vitro* diagnostic medical devices and accessories to such devices,];
 - (d) transplants or tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin ^{F12}, except for ^{F13}..., *in vitro* diagnostic medical devices and accessories to such devices]^{F14} save where medicinal products are incorporated as ancillary to the device];
 - ^{F15}(e) transplants or tissues or cells of animal origin, unless—
 - (i) a device is manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue, or
 - (ii) a product is ^{F16}... an *in vitro* diagnostic medical device, or an accessory to such a device;]
 - (f) cosmetic products governed by Council Directive [76/768/EEC](#)^{F17}, as amended ^{F18}, or
 - ^{F19}(g)

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 3 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

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

- F11** Words in reg. 3(c) substituted (10.3.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(a), **3(a)**
- F12** Words in reg. 3(d) inserted (10.3.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(a), **3(b)**
- F13** Words in reg. 3(d) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **3(a)**
- F14** Words in reg. 3(d) inserted (21.3.2010) by [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **3(b)**
- F15** Reg. 3(e) substituted (10.3.2007) by [The Medical Devices \(Amendment\) Regulations 2007 \(S.I. 2007/400\)](#), regs. 1(a), **3(c)**
- F16** Words in reg. 3(e)(ii) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **3(c)**
- F17** OJ No. L 262, 27.9.1976, p.169.
- F18** Council Directive 76/768/EEC was amended for the twenty-sixth time by Commission Directive 2000/41/EC (OJ No. L 145, 20.6.2000, p.25).
- F19** [Reg. 3\(g\)](#) omitted (21.3.2010) by virtue of [The Medical Devices \(Amendment\) Regulations 2008 \(S.I. 2008/2936\)](#), regs. 1(1), **3(d)**

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 3 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. 3 heading substituted by [S.I. 2019/791 reg. 3\(5\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(5)(a)(b) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 7)
- reg. 3 words substituted by [S.I. 2019/791 reg. 3\(5\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(5)(a)(b) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 7)

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))