

## STATUTORY INSTRUMENTS

# 2002 No. 618

## The Medical Devices Regulations 2002

### PART II

#### *General Medical Devices*

#### **[<sup>F1</sup>]<sup>F2</sup>Registration of persons placing general medical devices on the market**

##### **19.—(1) Paragraph (2) applies—**

- (a) in relation to relevant devices that are neither Class I devices nor custom-made devices, to—

- (i) a manufacturer with a registered place of business in Northern Ireland who, under their own name, places on the market in Northern Ireland any general medical device of any class, other than a system or procedure pack which is not CE marked;

<sup>F3</sup>(ii) .....

- (iii) a manufacturer's authorised representative who has a registered place of business in Northern Ireland;

- (iv) a manufacturer with a registered place of business in Great Britain whose authorised representative does not have a registered place of business in Northern Ireland;

- (b) in relation to Class I devices [<sup>F4</sup>that are not custom-made devices], to—

- (i) a manufacturer who places a device on the Northern Ireland market and has a registered place of business in Northern Ireland;

- (ii) an authorised representative with a registered place of business in Northern Ireland;

- (c) to a person with a registered place of business in Northern Ireland who sterilises before use any devices designed by their manufacturer to be sterilised before use.

##### **(2) For the purpose of enabling the Secretary of State to exercise the Secretary of State's functions under these Regulations, any person to whom this paragraph applies must—**

- (a) inform the Secretary of State of their address and registered place of business;

- (b) supply the Secretary of State with a description of each category of device concerned;

<sup>F5</sup>(c) .....

- (d) in the case of an authorised representative, supply the Secretary of State with—

- (i) written evidence that they have been designated as an authorised representative;

- (ii) details of the person who has so designated them; and

- (iii) where the person placing the devices concerned on the market is neither the manufacturer nor the authorised representative, the name and address of the registered place of business of the person placing the devices concerned on the market;

**Changes to legislation:** The Medical Devices Regulations 2002, Section 19 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

(e) inform the Secretary of State of any changes to the information referred to in sub-paragraphs (a) to (d) as and when such changes arise.

(3) The obligation in paragraph 2(2)(e) to inform the Secretary of State of any changes in relation to the information referred to in sub-paragraphs (2)(a) to (d) continues to apply following the passing of any of the dates specified in paragraph (4) that apply in respect of a particular case.

(4) The obligations in paragraph (2) begin to apply—

- (a) in the case of a device that is a Class I device and custom-made devices, on 1st January 2021;
- (b) in the case of a device that is a Class III or IIb implantable device, on 1st May 2021;
- (c) in the case of a device that is a Class IIa or Class IIb non-implantable device, on 1st September 2021.

<sup>F6</sup>(5) .....

<sup>F7</sup>(6) .....]]

#### Textual Amendments

- F1** Reg. 19 revoked (E.W.S) (30.4.2021) by S.I. 2002/618, **reg. 4D(1)** (as inserted by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **3(7)** (as amended by S.I. 2020/1478, regs. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F2** Reg. 19 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. 6**
- F3** Reg. 19(1)(a)(ii) omitted (N.I.) (27.7.2021) by virtue of [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **34(a)**
- F4** Words in reg. 19(1)(b) substituted (N.I.) (27.7.2021) by [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **34(b)**
- F5** Reg. 19(2)(c) omitted (N.I.) (27.7.2021) by virtue of [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **34(c)**
- F6** Reg. 19(5) omitted (N.I.) (27.7.2021) by virtue of [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **34(d)**
- F7** Reg. 19(6) omitted (N.I.) (27.7.2021) by virtue of [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021 \(S.I. 2021/905\)](#), regs. 1(2), **34(e)**

### Changes to legislation:

The Medical Devices Regulations 2002, Section 19 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.

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### 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))