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## STATUTORY INSTRUMENTS

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# 2002 No. 618

## The Medical Devices Regulations 2002

### PART I

#### *Introductory Provisions Relating to all Medical Devices*

#### **[<sup>F1</sup>Revocation, transitional and saving provisions in respect of Regulation (EU) 2017/745 <sup>F2</sup>and Regulation (EU) 2017/746]**

**3ZA.**—[<sup>F3</sup>(1) Subject to paragraph (2), Parts 2 to 7 only apply in Northern Ireland for the purpose of regulating qualifying devices.]

(2) The following provisions continue to apply in Northern Ireland in accordance with this paragraph <sup>F4</sup>...—

[<sup>F5</sup>(a) for the purposes of the registration of medical devices (whether or not they are qualifying devices) and persons placing medical devices on the market in Northern Ireland—

(i) regulation 19 (registration of persons placing general medical devices on the market),  
(ii) regulation 21B (registration of persons placing active implantable medical devices on the market),

(iii) regulation 44 (registration of persons placing in vitro diagnostic medical devices on the market or for performance evaluation), and

(iv) regulation 53 (fees in connection with the registration of devices and changes to registration details),

only apply until the date which is 24 months after the date of publication of the notice referred to in Article 34(3) of [Regulation \(EU\) 2017/745](#);

(aa) regulations 34A to 34D, 38A to 38C, 39A, 56A, 59 and 61 continue to apply in relation to coronavirus test devices whether or not they are qualifying devices;]

(b) Parts 5 to 7 [<sup>F6</sup>also] apply for purposes related to the designation of conformity assessment bodies for the purposes of a UK mutual recognition agreement.

(3) [<sup>F7</sup>For the purposes of this regulation], a device is a qualifying device if, by virtue of Article 120 of Regulation (EU) 2017/745 [<sup>F8</sup>or Article 110 of [Regulation \(EU\) 2017/746](#)]—

(a) it may be placed on the market, put into service or made available in Northern Ireland in accordance with the requirements of [<sup>F9</sup>Directive 90/385, Directive 93/42 or Directive 98/79, rather than [Regulation \(EU\) 2017/745](#) or [Regulation \(EU\) 2017/746](#); and]

(b) it is placed on the market, put into service or made available in Northern Ireland in accordance with, and subject to the requirements of and the arrangements set out in, Parts 2 <sup>F10</sup>... to 7.]

**Changes to legislation:** The Medical Devices Regulations 2002, Section 3ZA is up to date with all changes known to be in force on or before 17 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

### Textual Amendments

- F1** Reg. 3ZA inserted (N.I.) (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **32**
- F2** Words in reg. 3ZA heading inserted (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(a)**
- F3** Reg. 3ZA(1) substituted (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(b)**
- F4** Words in reg. 3ZA(2) omitted (21.3.2024) by virtue of The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(c)(i)**
- F5** Reg. 3ZA(2)(a)(aa) substituted for reg. 3ZA(2)(a) (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(c)(ii)**
- F6** Word in reg. 3ZA(2)(b) inserted (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(c)(iii)**
- F7** Words in reg. 3ZA(3) substituted (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(d)(i)**
- F8** Words in reg. 3ZA(3) inserted (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(d)(ii)**
- F9** Words in reg. 3ZA(3)(a) substituted (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(d)(iii)**
- F10** Words in reg. 3ZA(3)(b) omitted (21.3.2024) by virtue of The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **12(d)(iv)**

### Changes to legislation:

The Medical Devices Regulations 2002, Section 3ZA is up to date with all changes known to be in force on or before 17 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 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))