
STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART IV

In Vitro Diagnostic Medical Devices

[^{F1}Obligations in Part IV which are met by complying with obligations in Directive 98/79

44ZA.—(1) In this regulation—

- (a) any reference to an Article or Annex is a reference to that Article or Annex in Directive 98/79 as [^{F2}it had effect on 25 May 2022];
- (b) “Regulation 722/2012” means Commission Regulation (EU) 722/2012 as it applies in the European Union;
- (c) “CE marking” means the CE marking required by Article 16 and shown in Annex X;
- (d) “harmonised standard” is to be construed in accordance with Article 5.

(2) Where paragraph (3) applies regulations 34, 36(1) to (4), 37 and 40 are treated as being satisfied.

(3) [^{F3}Subject to to paragraph (3A),] this paragraph applies where, before placing a relevant device on the market, the manufacturer—

- (a) ensures—
 - (i) that the device meets the essential requirements set out in Annex I and, where applicable, Regulation (EU) 722/2012, which apply to it; or
 - (ii) that paragraphs (6) and (7) apply;
- (b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 9;
 - [ensures that any certificate issued by a notified body in connection with that conformity
- ^{F4}(ba) assessment procedure is valid by virtue of Article 110(2) of Regulation (EU) 2017/746;]
- (c) ensures that the documentation required by the relevant conformity assessment procedure is drawn up;
- (d) ensures that the technical and other relevant documentation required by a relevant conformity assessment procedure is prepared in or translated into English;
- (e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedure set out in Annexes III, IV, V, VI or VII;
- (f) [^{F5}has drawn up before 26 May 2022] an EU Declaration of Conformity in accordance with Article 9;
- (g) ensures that the declaration of conformity is prepared in or translated into English.

[

^{F6}(3A) Paragraph (3) only applies to a relevant device for which the conformity assessment procedure under Article 9 did not require the involvement of a notified body, if the conformity assessment procedure for that device under Article 48 of Regulation (EU) 2017/746 would require the involvement of a notified body.]

(4) Where paragraph (5) applies, regulation 43 is treated as being satisfied.

(5) This paragraph applies where before a relevant device intended for performance evaluation is made available in Great Britain for the purpose of a performance evaluation, the manufacturer—

- (a) has supplied the relevant written notice which must be in English in the form required by Sections 1 and 2 of Annex VIII;
- (b) has provided an undertaking to the Secretary of State to keep available the documentation required by Annex VIII for the period specified in Section 3 of Annex VIII;
- (c) has taken all necessary measures to ensure that the manufacturing process for the device produces devices in accordance with the documentation referred to in the first paragraph of Section 3 of Annex VIII.

(6) Where paragraph (7) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirements referred to in regulation 35(3) and (4).

(7) This paragraph applies where—

- (a) a relevant device conforms with a harmonised standard or part of a harmonised standard, which corresponds exactly to a designated standard or part of a designated standard; or
- (b) a relevant device is in conformity with a common technical specification.

(8) For the purpose of this regulation in regulations 36(5), 51 and 61(8), each reference to “UK marking” is to be read as a reference to “CE marking”.]

Textual Amendments

- F1** Regs. 44ZA, 44ZB inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/791), regs. 1(1), **6(10)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **46**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F2** Words in reg. 44ZA(1)(a) substituted (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023](#) (S.I. 2023/627), regs. 2(2), **9(2)**
- F3** Words in reg. 44ZA(3) inserted (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023](#) (S.I. 2023/627), regs. 2(2), **9(3)(a)**
- F4** Reg. 44ZA(3)(ba) inserted (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023](#) (S.I. 2023/627), regs. 2(2), **9(3)(b)**
- F5** Words in reg. 44ZA(3)(f) substituted (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023](#) (S.I. 2023/627), regs. 2(2), **9(3)(c)**
- F6** Reg. 44ZA(3A) inserted (1.7.2023) by [The Medical Devices \(Amendment\) \(Great Britain\) Regulations 2023](#) (S.I. 2023/627), regs. 2(2), **9(4)**

Changes to legislation:

There are outstanding changes not yet made by the [legislation.gov.uk](https://www.legislation.gov.uk) editorial team to The Medical Devices Regulations 2002. Any changes that have already been made by the team appear in the content and are referenced with annotations.

[View outstanding changes](#)

Changes and effects yet to be applied to :

- reg. 44ZA omitted by [S.I. 2024/221 reg. 19](#)

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](https://www.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](https://www.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](https://www.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](https://www.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](https://www.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](https://www.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. 2A(1A) inserted by [S.I. 2024/221 reg. 11\(b\)](#)
- reg. 3ZA(2)(a)(aa) substituted for reg. 3ZA(2)(a) by [S.I. 2024/221 reg. 12\(c\)\(ii\)](#)
- 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](https://www.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](https://www.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](https://www.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](https://www.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](https://www.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. 34D inserted by [S.I. 2024/221 reg. 17](#)
- 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))