STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART II

General Medical Devices

[F1[F2Obligations in Part II of these Regulations which are met by complying with obligations in Directive 93/42

19B.—(1) In this regulation—

(a) "the Directive" means Directive 93/42 **[**F3as it had effect on 25 May 2021**]** and any reference to an Article or Annex is a reference to that Article or Annex in the Directive F4...;

(b) "Regulation 722/2012" means Commission Regulation (EU) 722/2012 as it has effect in EU law;

(c) "CE marking" means the CE marking required by Article 17 and shown in Annex XII;

(d) "harmonised standard" is to be construed in accordance with Article 5.

(2) Where paragraph (3) applies regulations 8, 9, 10(1) to (4), 11 and 13 are treated as being satisfied.

(3) **[**F5Subject to paragraph (3A),**]** this paragraph applies where, before placing a relevant device other than a system or procedure pack, a custom-made device or a device intended for clinical investigation on the market, the manufacturer—

(a) ensures—

(i) that the device meets the essential requirements set out in Annex I and, where applicable, Regulation 722/2012, which apply to it; or

(ii) that paragraph (10) and (11) apply;

(b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 11;

[F6(ba) ensures that any certificate issued by a notified body in connection with that conformity assessment procedure is valid by virtue of Article 120(2) of Regulation (EU) 2017/745;**]**

(c) ensures that the documentation required by the conformity assessment procedure is drawn up;

(d) ensures that the technical and other relevant documentation required by the 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 II, III, IV, V, VI or VII;

(f) **[**F7has drawn up before 26 May 2021**]** an EU declaration of conformity in accordance with Article 11; and

(g) ensures that the declaration of conformity is prepared in or translated into English.

[

F8(3A) Paragraph (3) only applies to a class I device under the Directive if—

(a) the conformity assessment procedure under Article 11 required the involvement of a notified body; or

(b) the conformity assessment procedure for that device under Article 52 of Regulation (EU) 2017/745 would require the involvement of a notified body (if it were to be assessed under that regulation).**]**

(4) Where paragraph (5) applies, regulations 8 and 15 are treated as being satisfied.

(5) This paragraph applies where, before a custom-made device is placed on the market, the manufacturer—

(a) has drawn up a statement in English containing the information required by Section 1 and specified in Section 2.1 of Annex VIII, read with Regulation 722/2012;

(b) has undertaken to keep available to the Secretary of State (notwithstanding that the Secretary of State is not a competent authority) documentation allowing for an understanding of the design, manufacture and performance of the device, including the expected performances, so as to allow an assessment of conformity of the device with the requirements of the Directive;

(c) undertakes to the Secretary of State—

(i) to comply with Section 3.1 of Annex VIII;

(ii) to keep all documentation required by Annex VIII available in accordance with Section 4 of Annex VIII; and

(iii) to pass the statement mentioned in subparagraph (a) on with the custom-made device so that it may be made available to the patient on request.

(6) Where paragraph (7) applies, regulations 8 and 14 are treated as being satisfied.

(7) This paragraph applies where before a system or procedure pack is placed on the market, the manufacturer—

(a) has complied with Article 12(2);

(b) has complied with Article 12(3) and with the procedure in Annex II or V;

[F9(ba) ensures that any certificate in relation to the system or procedure pack or a device within it that was issued by a notified body under the Directive is valid by virtue of Article 120(2) of Regulation (EU) 2017/745;

(bb) ensures that the declarations required by Article 12 were drawn up before 26 May 2021;**]**

(c) undertakes to keep the declarations required by Article 12 for the period specified in Article 12(4); F10...

(d) ensures that the system or procedure pack is accompanied by the information referred to in point 13 of Annex I which must be in **[**F11English; and**]**

[F12(e) ensures that the system or procedure pack does not contain a class I device under the Directive for which—

(i) the conformity assessment procedure under Article 11 did not require the involvement of a notified body; and

(ii) the conformity assessment procedure under Article 52 of Regulation (EU) 2017/745 would not require the involvement of a notifed body (if it were to be assessed under that regulation).**]**

(8) Where paragraph (9) applies, regulations 8 and 16 are treated as being satisfied.

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

(a) has provided the Secretary of State with the relevant written notice which must be in English in the form of the Statement required by Sections 1 and 2.2 of Annex VIII;

(b) undertakes to keep available the documentation referred to in Section 3.2 of Annex VIII for the period specified in Section 4 of that Annex; and

(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 paragraph 3.1 of Annex VIII.

(10) Where paragraph (11) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirement referred to in regulation 9(4).

(11) This paragraph applies where 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.

(12) For the purpose of this regulation in regulations 10(5), 51 and 61(8), each reference to "UK marking" is to be read as a reference to "CE marking".**]]**

Textual Amendments

F1 Reg. 19B omitted (N.I.) (21.3.2024) by virtue of The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **14**

F2 Regs. 19B, 19C inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(11)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **24**); 2020 c. 1, **Sch. 5 para. 1(1)**

F3 Words in reg. 19B(1)(a) inserted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(2)(a)**

F4 Words in reg. 19B(1)(a) omitted (E.W.S.) (1.7.2023) by virtue of The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(2)(b)**

F5 Words in reg. 19B(3) inserted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(3)(a)**

F6 Reg. 19B(3)(ba) inserted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(3)(b)**

F7 Words in reg. 19B(3)(f) substituted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(3)(c)**

F8 Reg. 19B(3A) inserted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(4)**

F9 Reg. 19B(7)(ba)(bb) inserted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(5)(a)**

F10 Word in reg. 19B(7)(c) omitted (E.W.S.) (1.7.2023) by virtue of The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(5)(b)**

F11 Words in reg. 19B(7)(d) substituted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(5)(c)**

F12 Reg. 19B(7)(e) inserted (E.W.S.) (1.7.2023) by The Medical Devices (Amendment) (Great Britain) Regulations 2023 (S.I. 2023/627), regs. 2(2), **6(5)(d)**

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