STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART II

General Medical Devices

Determining compliance of general medical devices with relevant essential requirements E+W+S

9.—(1) In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) Where confirmation of conformity with the essential requirements must be based on clinical data, such data must be established in accordance with the requirements set out in Annex X.

(3) In the case of a relevant device which is being or has been put into service—

(a) the essential requirements specified in Sections 8.7 and 13 of Annex I with regard to information on the packaging and on any label are complied with only if such information is in English (whether or not it is also in another language and whether or not the device is for professional use); and

(b) the essential requirements specified in Sections 11.4 and 13 of Annex I with regard to instructions for use are complied with only if—

(i) such instructions are in English [F1]...

[F2](ii) . . . . . .

(4) A relevant device shall be treated as complying with an essential requirement if it conforms as respects that requirement to a relevant **[**[F3]designated standard**]**, unless there are reasonable grounds for suspecting that it does not comply with that requirement.

(5) A custom-made device—

(a) in respect of which the conditions specified in Annex VIII are satisfied; and

(b) in the case of a Class IIa, Class IIb and Class III device, which is accompanied by the statement required by Section 1 of Annex VIII,

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

[[F4](5A) When a custom-made device is supplied to a patient, the healthcare professional who writes the prescription for the custom-made device shall, in relation to each patient that they supply with such a device—

(a) ensure that the patient is aware that they may request the statement containing the information required by Sections 1 and 2 of Annex VIII; and

(b) ensure that the statement containing the information required by Sections 1 and 2 of Annex VIII is made available to the patient on request.**]**

(6) Where, in accordance with Section 2.1 of Annex VIII, a manufacturer of a custom-made device, or **[**F5their UK responsible person**]**, has indicated that specified essential requirements have not been fully met, and has given proper grounds as to why they have not been fully met, those specified essential requirements are no longer to be treated as relevant essential requirements for that device.

(7) A device intended for clinical investigation in respect of which—

(a) the conditions specified in Annex VIII are satisfied;

(b) notice has been given under regulation 16(1); and

(c) either—

(i) no notice has been given under regulation 16(4) within the period of 60 days there referred to, or

(ii) notice has been given under regulation 16(5),

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

(8) A single-use combination product shall be taken to comply with the relevant essential requirements if the medical device which forms part of that product only complies with the requirements set out in Annex I F6... that relate to safety and performance, unless the medicinal product which forms part of that product is liable to act on the human body with action ancillary to that of the medical device, in which case the single-use combination product must comply with all the relevant essential requirements which apply to it.

[F7(9) Where a device is intended by the manufacturer to be used in conjunction with both the provisions in **[**F8Regulation (EU) 2016/425 of the European Parliament and of the Council of 9th March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC**]** and Directive 93/42, the relevant basic health and safety requirements of **[**F9Regulation (EU) 2016/425**]** shall also be fulfilled.**]**

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. 9(3)(b)(i) 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), **4(6)(a)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F2 Reg. 9(3)(b)(ii) 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), **4(6)(a)(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. 9(4) substituted (E.W.S.) (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 9**

F4 Reg. 9(5A) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **6(a)**

F5 Words in reg. 9(6) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6)(aa)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **13**); 2020 c. 1, **Sch. 5 para. 1(1)**

F6 Words in reg. 9(8) omitted (E.W.S.) (31.12.2020) by virtue of y The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6)(ab)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **13**); 2020 c. 1, **Sch. 5 para. 1(1)**

F7 Reg. 9(9) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **6(b)**

F8 Words in reg. 9(9) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6)(b)(i)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

F9 Words in reg. 9(9) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **4(6)(b)(ii)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 2); 2020 c. 1, Sch. 5 para. 1(1)

Determining compliance of general medical devices with relevant essential requirements N.I.

9.—(1) In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) Where confirmation of conformity with the essential requirements must be based on clinical data, such data must be established in accordance with the requirements set out in Annex X.

(3) In the case of a relevant device which is being or has been put into service—

(a) the essential requirements specified in Sections 8.7 and 13 of Annex I with regard to information on the packaging and on any label are complied with only if such information is in English (whether or not it is also in another language and whether or not the device is for professional use); and

(b) the essential requirements specified in Sections 11.4 and 13 of Annex I with regard to instructions for use are complied with only if—

(i) such instructions are in English or another Community language, and

(ii) if the instructions are not in English, any packaging, label or promotional literature carries a clear statement in English stating the language in which the instructions are given.

(4) A relevant device shall be treated as complying with an essential requirement if it conforms as respects that requirement to a relevant national standard, unless there are reasonable grounds for suspecting that it does not comply with that requirement.

(5) A custom-made device—

(a) in respect of which the conditions specified in Annex VIII are satisfied; and

(b) in the case of a Class IIa, Class IIb and Class III device, which is accompanied by the statement required by Section 1 of Annex VIII,

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

[F10(5A) When a custom-made device is supplied to a patient, the healthcare professional who writes the prescription for the custom-made device shall, in relation to each patient that they supply with such a device—

(a) ensure that the patient is aware that they may request the statement containing the information required by Sections 1 and 2 of Annex VIII; and

(b) ensure that the statement containing the information required by Sections 1 and 2 of Annex VIII is made available to the patient on request.**]**

(6) Where, in accordance with Section 2.1 of Annex VIII, a manufacturer of a custom-made device, or his authorised representative, has indicated that specified essential requirements have not

been fully met, and has given proper grounds as to why they have not been fully met, those specified essential requirements are no longer to be treated as relevant essential requirements for that device.

(7) A device intended for clinical investigation in respect of which—

(a) the conditions specified in Annex VIII are satisfied;

(b) notice has been given under regulation 16(1); and

(c) either—

(i) no notice has been given under regulation 16(4) within the period of 60 days there referred to, or

(ii) notice has been given under regulation 16(5),

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

(8) A single-use combination product shall be taken to comply with the relevant essential requirements if the medical device which forms part of that product only complies with the requirements set out in Annex I of Directive 93/42 that relate to safety and performance, unless the medicinal product which forms part of that product is liable to act on the human body with action ancillary to that of the medical device, in which case the single-use combination product must comply with all the relevant essential requirements which apply to it.

[[F11](9) Where a device is intended by the manufacturer to be used in conjunction with both the provisions in Council Directive 89/686/EEC on the approximation or the laws of the Member States relating to personal protective equipment and Directive 93/42, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled.**]**

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

Textual Amendments

F10 Reg. 9(5A) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **6(a)**

F11 Reg. 9(9) inserted (21.3.2010) by The Medical Devices (Amendment) Regulations 2008 (S.I. 2008/2936), regs. 1(1), **6(b)**

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 9 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))