STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART IV

In Vitro Diagnostic Medical Devices

Manufacturers etc. and conformity assessment procedures for *in vitro* diagnostic medical devices E+W+S

41.—(1) A manufacturer of a relevant device or, where applicable, **[**F1their UK responsible person**]** who is required to follow, or follows or has followed a conformity assessment procedure set out in **[**F2this Part**]** shall observe the manufacturer's obligations set out in that procedure **[**F3that apply to the manufacturer or, as the case may be, their UK responsible person**]**.

(2) A manufacturer of a relevant device or, where applicable, **[**F1their UK responsible person**]** shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with **[**F2this Part**]** at an intermediate stage of manufacture of the device.

(3) A manufacturer or, where applicable, **[**F1their UK responsible person**]** shall, in respect of any relevant device which the manufacturer has placed on the market or put into service, keep available for inspection by the Secretary of State—

(a) the declaration of conformity for that device;

(b) the technical documentation referred to in Annexes III to VIII relating to that device; and

(c) the decisions, reports and certificates of **[**F4approved bodies**]** relating to that device,

for a period ending five years after the manufacture of the last product.

(4) A person who in the course of manufacturing relevant devices or devices for performance evaluation removes, collects, or uses tissues, cells or substances of human origin shall, in the course of removing, collecting or using those tissues, cells or substances act in accordance with the principles laid down in the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine M1.

F5(5) . . . . . .

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. 41 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), **reg. 6(6)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **42**); 2020 c. 1, **Sch. 5 para. 1(1)**

F2 Words in reg. 41 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), **reg. 6(6)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **42**); 2020 c. 1, **Sch. 5 para. 1(1)**

F3 Words in reg. 41(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), **reg. 6(6)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **42**); 2020 c. 1, **Sch. 5 para. 1(1)**

F4 Words in reg. 41(3)(c) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), **reg. 6(6)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **42**); 2020 c. 1, **Sch. 5 para. 1(1)**

F5 Reg. 41(5) omitted (E.W.S.) (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 1 para. 18**

Marginal Citations

M1 Council of Europe (ETS No. 164), Orviedo, 4.4.1997.

Manufacturers etc. and conformity assessment procedures for *in vitro* diagnostic medical devices N.I.

41.—(1) A manufacturer of a relevant device or, where applicable, his authorised representative who is required to follow, or follows or has followed a conformity assessment procedure set out in Directive 98/79 shall observe the manufacturer's obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, his authorised representative shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 98/79 at an intermediate stage of manufacture of the device.

(3) A manufacturer or, where applicable, his authorised representative shall, in respect of any relevant device which the manufacturer has placed on the market or put into service, keep available for inspection by the Secretary of State—

(a) the declaration of conformity for that device;

(b) the technical documentation referred to in Annexes III to VIII relating to that device; and

(c) the decisions, reports and certificates of notified bodies relating to that device,

for a period ending five years after the manufacture of the last product.

(4) A person who in the course of manufacturing relevant devices or devices for performance evaluation removes, collects, or uses tissues, cells or substances of human origin shall, in the course of removing, collecting or using those tissues, cells or substances act in accordance with the principles laid down in the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine [M2].

(5) Until the European databank referred to in article 12 has been established, the manufacturer or, where applicable, his authorised representative shall, in respect of any relevant device which the manufacturer has placed on the market **[**[F6]in Northern Ireland**]**, provide the Secretary of State with the data referred to in article 12(1)(a), and that data shall be provided in English.

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

F6 Words in reg. 41(5) 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. 14**

Marginal Citations

M2 Council of Europe (ETS No. 164), Orviedo, 4.4.1997.

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 41 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 :

- reg. 41(5) words omitted by S.I. 2019/791 reg. 6(6)(a) (This amendment not applied to legislation.gov.uk. Reg. 6(6) substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 42)
- reg. 41(5) words omitted by S.I. 2019/791 reg. 6(6)(b) (This amendment not applied to legislation.gov.uk. Reg. 6(6) substituted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 42)

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))