STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART II

General Medical Devices

[F1UK marking] of general medical devices E+W+S

10.—(1) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless, where practical and appropriate, that device or its sterile pack bears a [F2UK marking] which—

(a) meets the requirements set out in [F3Annex 2 of Regulation (EC) No 765/2008];

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant [F4approved body] or conformity assessment body identification number for that device.

(2) Subject to regulations 12 and 14, no person shall supply a relevant device unless, where practical and appropriate, that device or its sterile pack bears a [F5UK marking] which—

(a) meets the requirements set out in [F6Annex 2 of Regulation (EC) No 765/2008];

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant [F7approved body] or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless [F8a UK marking meeting the requirements of Annex 2 of Regulation (EC) No 765/2008], appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for the device,

and that [F9UK marking] is accompanied by any relevant [F10approved body] or conformity assessment body identification number for that device.

(4) Subject to regulations 12 and 14, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless [F11a UK marking meeting the requirements of Annex 2 of Regulation (EC) No 765/2008], appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for the device,

and that [F12UK marking] is accompanied by any relevant [F13approved body] or conformity assessment body identification number for that device.

(5) No person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

(a) a relevant device or its sterile pack;

(b) the instructions for use for a relevant device; or

(c) any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the **[**[F14]UK marking**]** or which reduces the visibility or the legibility of the **[**[F14]UK marking**]**.

[[F15](6) In this regulation, where a device is required to bear a UK marking which meets the requirements of Annex 2 of Regulation (EU) No 765/2008, the requirement as to the minimum size of the UK marking specified in section 3 of that Annex is to be understood—

(a) as not applying where, having regard to the small size of the device, it is not possible for the device to bear a marking of that minimum size; and

(b) as allowing a device to bear a UK marking of a size less than that minimum size provided that mark continues to meet the requirements as to visibility, legibility and indelibility in paragraphs (1) and (2).**]**

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. 10 heading 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(6A)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F2 Words in reg. 10(1) 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(6A)(b)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F3 Words in reg. 10(1)(a) 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(6A)(b)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F4 Words in reg. 10(1)(c) 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(6A)(b)(iii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F5 Words in reg. 10(2) 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(6A)(c)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F6 Words in reg. 10(2)(a) 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(6A)(c)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F7 Words in reg. 10(2)(c) 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(6A)(c)(iii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F8 Words in reg. 10(3) 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(6A)(d)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F9 Words in reg. 10(3) 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(6A)(d)(ii)(aa)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F10 Words in reg. 10(3) 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(6A)(d)(ii)(bb)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F11 Words in reg. 10(4) 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(6A)(e)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F12 Words in reg. 10(4) 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(6A)(e)(Ii)(aa)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F13 Words in reg. 10(4) 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(6A)(e)(ii)(bb)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F14 Words in reg. 10(5) 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(6A)(f)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

F15 Reg. 10(6) inserted (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. 10**

CE marking of general medical devices N.I.

10.—(1) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless, where practical and appropriate, that device or its sterile pack bears a CE marking which—

(a) meets the requirements set out in Annex XII;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(2) Subject to regulations 12 and 14, no person shall supply a relevant device unless, where practical and appropriate, that device or its sterile pack bears a CE marking which—

(a) meets the requirements set out in Annex XII;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulations 12 and 14, no person shall place on the market or put into service a relevant device unless a CE marking, meeting the requirements set out in Annex XII, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for the device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(4) Subject to regulations 12 and 14, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless a CE marking, meeting the requirements set out in Annex XII, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for the device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(5) No person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

(a) a relevant device or its sterile pack;

(b) the instructions for use for a relevant device; or

(c) any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the CE marking or which reduces the visibility or the legibility of the CE marking.

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