SCHEDULE 2

Regulation 3

Amendment of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

Interpretation

1. In this Schedule, "the 2002 Regulations" means the Medical Devices Regulations 2002 [M1].

Commencement Information

I1 Sch. 2 para. 1 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M1 S.I. 2002/618; relevant amendments were made by S.I. 2019/791.

Amendment of regulation 3 (amendment of Part I of the 2002 Regulations)

2.—(1) Regulation 3 is amended as follows.

(2) In paragraph (6), in inserted regulation 3A of the 2002 Regulations (designated standard)—

(a) for paragraph (1), substitute—

"(1) In [F1Parts II, III and IV] of these Regulations, a "designated standard" means—

(a) a technical specification which is—

(i) adopted by a recognised standardisation body, for repeated or continuous application with which compliance is not compulsory; and

(ii) designated by the Secretary of State by publishing a reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate; or

(b) a monograph of the European Pharmacopoeia (in particular on surgical sutures and on the interaction between medicinal products and materials used in devices containing medicinal products) which has been published in the Official Journal of the European Union.";

(b) in paragraph (3)(b), for "(CENLAC)" substitute, " (CENELEC) ";

(c) for paragraph (8), substitute—

"(8) In this regulation—

(a) a reference to a "device" is a reference to a medical device or its accessory or an in vitro diagnostic medical device or its accessory to which these Regulations apply;

(b) a reference to "the European Pharmacopoeia" is a reference to the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia."

M2

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F2(3) . . . . . .

F1 Words in Sch. 2 para. 2(2)(a) substituted (9.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), regs. 1(2), **4(2)(a)(i)**

F2 Sch. 2 para. 2(3) omitted (9.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), regs. 1(2), **4(2)(a)(ii)**

Commencement Information

I2 Sch. 2 para. 2 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M2 Council of Europe (ETS No. 050), Strasbourg, 22.07.1964.

Amendment of regulation 4 (amendment of Part II of the 2002 Regulations)

3. In regulation 4(4), in inserted regulation 7A of the 2002 Regulations (registration of persons placing general medical devices on the market), after paragraph (2), insert—

"(2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.".

Commencement Information

I3 Sch. 2 para. 3 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 5 (amendment of Part III of the 2002 Regulations)

4. In regulation 5(3), in inserted regulation 21A of the 2002 Regulations (registration of persons placing active implantable medical devices on the market) after paragraph (2), insert—

"(2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.".

Commencement Information

I4 Sch. 2 para. 4 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 6 (amendment of Part IV of the 2002 Regulations)

5. In regulation 6(3), in inserted regulation 33A of the 2002 Regulations (registration etc. of persons placing in vitro diagnostic medical devices on the market) after paragraph (2), insert—

"(2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.".

Commencement Information

I5 Sch. 2 para. 5 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PROSPECTIVE

Amendment of regulation 7 (amendment of Part V of the 2002 Regulations)

[F3]6. . . . . . .

F3 Sch. 2 para. 6 omitted (9.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), regs. 1(2), **4(2)(b)**

Amendment of regulation 8 (amendment of Part VI of the 2002 Regulations)

7. In regulation 8, for paragraph (4), substitute—

"(4) In regulation 55 [M3] (fees payable in connection with the designation etc. of EC conformity assessment bodies)—

(a) in the heading omit "EC";

(b) in paragraph (1), for "an EC CAB" substitute " a CAB ";

(c) in paragraph (3)—

(i) for "an EC CAB" substitute " a CAB ";

(ii) for "the Mutual Recognition Agreements" substitute " a mutual recognition agreement ".".

Commencement Information

I6 Sch. 2 para. 7 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M3 2018 c. 16.

Amendment of regulation 9 (amendment of Part VII of the 2002 Regulations)

8. In regulation 9(3) (amendment of regulation 60 of the 2002 Regulations), for sub-paragraph (d), substitute—

"(d) in paragraph (4)—

(i) for "an authorised representative of a manufacturer of a device" substitute " a UK responsible person ";

(ii) for "the single authorised representative of the manufacturer" substitute " a UK responsible person ".".

Commencement Information

I7 Sch. 2 para. 8 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PROSPECTIVE

Amendment of regulation 10 (insertion of Part VIII into the 2002 Regulations)

[F4]9. . . . . . .

F4 Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), regs. 1(2), **4(2)(c)**

PROSPECTIVE

Amendment of regulation 11 (insertion of new Part IX into the 2002 Regulations)

[F4]10. . . . . . .

F4 Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), regs. 1(2), **4(2)(c)**

PROSPECTIVE

Amendment of regulation 12 (new Schedules to the 2002 Regulations)

[F4]11. . . . . . .

F4 Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), regs. 1(2), **4(2)(c)**

Status:
This version of this schedule contains provisions that are prospective.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, SCHEDULE 2.