STATUTORY INSTRUMENTS

2019 No. 791

The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

PART 1

Amendment of the 2002 Regulations

Amendment of Part VII of the 2002 Regulations

9.—(1) Part VII of the 2002 Regulations is amended as follows.

(2) In regulation 59 [M1](interpretation of Part VII)—

(a) omit the definition of "registrable device";

(b) in the definition of "relevant device" after "IV" insert " or a device for the purposes of Part VIII or IX. ".

(3) [M2]In regulation 60 (designation etc. of authorised representatives)—

(a) for the heading substitute " Status of UK responsible person ";

(b) omit paragraphs (1) and (2);

(c) for paragraph (3), substitute—

"(3) A UK responsible person—

(a) may be proceeded against as a person placing the device on the market for the purposes of these regulations;

(b) in relation to the supply of the device to a person within the United Kingdom after it has been placed on the market, may be proceeded against as a person supplying the device after it has been placed on the market.".

[[F1](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 ".**]**

[[F2](4) In regulation 61 (enforcement etc.)—

(a) for "CE marking" in both places substitute "UK marking";

(b) in paragraph (8)(a)(i), after "essential requirement" insert ", a general safety and performance requirement";

(c) in paragraph (8)(a)(ii), omit "set out in the Medical Devices Directives";

(d) in paragraph (8)(a)(ii)(aa), for "his authorised representative" substitute "their UK responsible person".**]**

(5) In regulation 62 (compliance notices) in paragraph (1)—

(i) after "performance evaluation" insert " or study ";

(ii) for "the manufacturer or his authorised representative" substitute " any person ";

[F3(iii) in sub-paragraph (c) omit "and, where applicable any relevant provision of the Medical Devices Directives".]

(6) In regulation 63 M3 (restriction notices) in paragraph (1)—

(i) in sub-paragraph (a), after "performance evaluation" insert " or study ";

(ii) in sub-paragraph (b), after "performance evaluation" insert " or study ".

[F4(6A) In regulation 64 (notification of decisions etc)—

(a) in paragraph (1)(c), for "him or his authorised representative" substitute "the applicant or the applicant's UK responsible person";

(b) in paragraph (2)—

(i) for "a UK notified body" substitute "an approved body";

(ii) for "his authorised representative" substitute "their UK responsible person".]

(7) Omit regulation 65(centralised system of records etc.).

(8) In regulation 67 M4 (review), for "2019" substitute " 2025 ".

(9) Omit Schedule 1 M5 (association agreements).

(10) For Schedule 2 M6 (mutual recognition agreements) substitute—

"SCHEDULE 2 Regulation 1A

Mutual Recognition Agreement countries

— Australia

— New Zealand

— Canada

— The United States of America

— The Swiss Confederation".

Textual Amendments

F1 Reg. 9(3)(d) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 2 para. 8**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Reg. 9(4) substituted (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. 2 para. 51**

F3 Reg. 9(5)(iii) inserted (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. 2 para. 52**

F4 Reg. 9(6A) inserted (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. 2 para. 53**

Commencement Information

I1 Reg. 9(1)(3)-(10) in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(1)

I2 Reg. 9(2) in force at 1.5.2021, see reg. 1(2)(e) (as amended by S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2(c)**)

Marginal Citations

M1 Regulation 59 was amended by S.I. 2003/1697.

M2 Regulation 60 was amended by S.I. 2008/2936.

M3 Regulation 63 was amended by S.I. 2008/2936.

M4 Regulation 67 was inserted by S.I. 2013/2327.

M5 Schedule 1 was amended by 2013/2327.

M6 Schedule 2 was amended by S.I. 2013/2327.

Changes to legislation:
There are currently no known outstanding effects for the The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, Section 9.