STATUTORY INSTRUMENTS

2019 No. 791

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

PART 1

Amendment of the 2002 Regulations

Amendment of Part VI of the 2002 Regulations

8.—(1) Part VI of the 2002 Regulations is amended as follows.

[[F1](2) In regulation 53 (fees in connection with the registration of devices and changes in registration details) for "regulation 19 or 44" substitute "regulation 7A, 19, 21A, 33A or 44".

(3) In regulation 54 (fees payable in connection with the designation of UK notified bodies)—

(a) for the heading substitute "Fees payable in connection with the designation of approved bodies";

(b) in paragraph (1) for "a notified body" substitute "an approved body";

(c) in paragraph (3) for "the Mutual Recognition Agreements" in both places substitute "a mutual recognition agreement";

(d) in paragraph (3C) for "A UK notified body" substitute "An approved body";

(e) in paragraph (3D)—

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

(ii) for "the UK notified body" substitute "the approved body";

(f) in paragraph (3E) for "A UK notified body" substitute "An approved body".**]**

[[F2](4) In regulation 55 (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 ".**]**

[[F3](4A) In regulation 56 (fees payable in relation to clinical investigation notices), in paragraph (2), for "his authorised representative" substitute "their UK responsible person".**]**

[[F4](5) In regulation 58 (waivers, reductions and refunds)—

(a) in paragraph (2)(b)(i) for "a notified body" substitute "an approved body";

(b) in paragraph (2)(b)(ii) for "an EC CAB" substitute "a CAB".**]**

F1 Reg. 8(2)(3) 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. 48**

F2 Reg. 8(4) 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. 7**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Reg. 8(4A) 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. 49**

F4 Reg. 8(5) 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. 50**

Commencement Information

I1 Reg. 8(1)(3)-(5) 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. 8(2) in force at 1.5.2021, see reg. 1(2)(d) (as amended by S.I. 2020/1478, reg. 1(3), **Sch. 2 para. 2(c)**)

Changes to legislation:
There are currently no known outstanding effects for the The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, Section 8.