STATUTORY INSTRUMENTS

2019 No. 791

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

PART 1

Amendment of the 2002 Regulations

Amendment of Part V of the 2002 Regulations

[F1 7.—(1) Part V of the 2002 Regulations is amended as follows.

(2) In the Part V heading for "Notified Bodies" substitute "Approved Bodies".

(3) Before regulation 45 insert—

"**Meaning of approved body and UK notified body**

A45.—(1) An approved body is a conformity assessment body which—

(a) has been designated by the Secretary of State pursuant to the procedure set out in regulation 45 (designation etc. of approved bodies); or

(b) immediately before IP completion day was a UK notified body in respect of which the Secretary of State has taken no action under regulation 45(5) to withdraw a designation.

(2) In this regulation—

"UK notified body" means a body which the Secretary of State had before IP completion day notified to the European Commission in accordance with Article 3(7) of Commission Implementing Regulation (EU) 920/2013 or under Article 15 of Directive 98/79.".".

(4) In regulation 45 (designation etc. of UK notified bodies)—

(a) in the heading for "UK notified bodies" substitute "approved bodies";

(b) in paragraph (1)—

(i) for "article 11 of Directive 90/385, article 16 of Directive 93/42 or article 15 of Directive 98/79" substitute "these Regulations";

(ii) for "a notified body" substitute "an approved body";

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

(c) in the opening words of paragraph (2) for "a notified body" substitute "an approved body";

(d) in paragraph (2)(a)—

(i) for "Directive 90/385" substitute "Part III";

(ii) for "notified bodies set out in Annex 8 of that Directive" substitute "approved bodies set out in Annex 8 of Directive 90/385";

(e) in paragraph (2)(b)—

(i) for "Directive 93/42" substitute "Part II";

(ii) for "notified bodies set out in Annex XI of that Directive" substitute "approved bodies set out in Annex XI of Directive 93/42";

(f) in paragraph (2)(c)—

(i) for "Directive 98/79" substitute "Part IV";

(ii) for "notified bodies set out in Annex IX of that Directive" substitute "approved bodies set out in Annex IX of Directive 98/79";

(g) in paragraph (2)(d) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement";

(h) in paragraph (4) for "a UK notified body" substitute "an approved body";

(i) in paragraph (5)(c) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement";

(j) in paragraph (6)—

(i) for "the notified body's request" substitute "the approved body's request";

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

(k) in paragraph (7), in the opening words, for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement";

(l) in paragraph (8)—

(i) in the opening words for "a UK notified body" substitute "an approved body";

(ii) in sub-paragraph (b) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement".

(5) In regulation 46 (choice of notified bodies and conformity assessment bodies)—

(a) for the heading substitute "Choice of approved bodies and conformity assessment bodies";

(b) for "a notified body" substitute "an approved body"

(c) for "his authorised representative" substitute "the manufacturer's UK responsible person";

(d) for "any notified body" substitute "any approved body".

(6) In regulation 47 (general matters relating to UK notified bodies)—

(a) for the heading substitute "General matters relating to approved bodies";

(b) in paragraph (1)—

(i) for "A UK notified body" substitute "An approved body";

(ii) for "his authorised representative" substitute "the manufacturer's UK responsible person";

(iii) for "a notified body" substitute "an approved body";

(iv) for "the Medical Devices Directives" substitute "these Regulations";

(c) in paragraph (2)—

(i) for "his authorised representative" substitute "the manufacturer's UK responsible person";

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

(d) in paragraph (3)—

(i) for "his authorised representative supplies to a notified body" substitute "the manufacturer's UK responsible person supplies to an approved body";

(ii) for "the Medical Devices Directives" substitute "these Regulations";

(iii) omit "if the notified body is within the United Kingdom";

(iv) omit "or some other Community language acceptable to the notified body concerned";

(e) in paragraph (4)—

(i) for "A UK notified body" substitute "An approved body";

(ii) for "other notified bodies" substitute "other approved bodies";

(f) in paragraph (5)—

(i) in the opening words for "a UK notified body" substitute "an approved body";

(ii) in sub-paragraph (a) for "the Medical Devices Directives" substitute "these Regulations";

(iii) in the words after sub-paragraph (b) for "notified body", both times those words occur, substitute "approved body";

(g) in paragraph (6)—

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

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

(h) in paragraph (8)—

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

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

(7) After regulation 47 insert—

"**Register of approved bodies**

47A.—(1) The Secretary of State must ensure that—

(a) each approved body is assigned an identification number; and

(b) there is a register of—

(i) approved bodies;

(ii) their approved body identification number;

(iii) the tasks for which they have been designated; and

(iv) any restrictions on those tasks.

(2) The Secretary of State must ensure that the register referred to in paragraph (1) is maintained and made publicly available.

(3) The Secretary of State may authorise the United Kingdom Accreditation Service to compile and maintain the register in accordance with paragraph (1)(b).".

(8) In regulation 48 (designation etc. of EC conformity assessment bodies)—

(a) in the heading omit "EC";

(b) in paragraph (1)—

(i) for "the Mutual Recognition Agreements" substitute "a mutual recognition agreement";

(ii) omit "European Community";

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

(c) in paragraph (2)—

(i) for "an EC CAB" in both places substitute "a CAB";

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

(d) in paragraph (4) for "an EC CAB" substitute "a CAB";

(e) in paragraph (5)(b)—

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

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

(f) in paragraph (6) omit "EC" in both places;

(g) in paragraph (7), in the opening words—

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

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

(h) in paragraph (8)—

(i) for "an EC CAB" in both places substitute "a CAB";

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

(9) In regulation 49 (fees charged by UK notified bodies and EC conformity assessment bodies)—

(a) for the heading substitute "Fees charged by approved bodies and conformity assessment bodies";

(b) in paragraph (1), in the opening words for "A UK notified body or EC CAB" substitute "An approved body or CAB";

(c) for paragraph (1)(a) substitute—

"(a) in the case of an approved body, performing the functions of an approved body or an importing Party under these Regulations or a mutual recognition agreement; and";

(d) in paragraph (1)(b)—

(i) for "an EC CAB" in both places it occurs substitute "a CAB";

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

(e) in paragraph (3)—

(i) in the opening words for "UK notified body or EC CAB" substitute "approved body or CAB";

(ii) in sub-paragraph (a) for "notified body" substitute "approved body";

(f) in paragraph (4) for "UK notified body or EC CAB" substitute "approved body or CAB".

(10) In regulation 50 (products incorrectly marked with a notified body or conformity assessment body number)—

(a) in the heading for "a notified body" substitute "an approved body";

(b) in paragraph (1) for "a notified body" in each place it occurs substitute "an approved body";

(c) in paragraph (2)—

(i) for "a notified body" each place it occurs substitute "an approved body";

(ii) in sub-paragraph (b) for "the notified body" substitute "the approved body";

(d) in paragraph (3)(a) for "a notified body" substitute "an approved body";

(e) in paragraph (3)(b) for "notified body" in both places substitute "approved body";

(f) in paragraph (4) for "a notified body" substitute "an approved body".

(11) In regulation 51 (products incorrectly marked with a CE marking) and in the heading, for "CE marking" in each place it occurs substitute "UK marking".**]**

Textual Amendments

F1 Reg. 7 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. 47**

Commencement Information

I1 Reg. 7 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)

Changes to legislation:
There are currently no known outstanding effects for the The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, Section 7.