

SCHEDULE 2

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

Substitution of regulation 7

47. For regulation 7 substitute—

“Amendment of Part V of the 2002 Regulations

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”.