STATUTORY INSTRUMENTS

2019 No. 791

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

PART 1

Amendment of the 2002 Regulations

Amendment of Part IV of the 2002 Regulations

6.—(1) Part IV of the 2002 Regulations is amended as follows.

F1(2) . . . . . .

(3) After regulation 33 insert—

"**Registration etc. of persons placing in vitro diagnostic medical devices on the market**

33A.—(1) No person may place a relevant device on the market in accordance with this Part F2... unless that person—

(a) is established in **[**F3Great Britain**]**; and

(b) has complied with paragraph (2).

[F4(2) A person who places a relevant device on the market complies with this paragraph if, before placing the relevant device on the market—

(a) where—

(i) that person is the manufacturer of that device and is based in Great Britain, the person informs the Secretary of State of the address of their registered place of business in Great Britain;

(ii) that person is the manufacturer of that device and is based outside the United Kingdom, the manufacturer appoints a sole UK responsible person, and that UK responsible person provides the Secretary of State with written evidence that they have the manufacturer's authority to act as their UK responsible person; or

(iii) that person is not the manufacturer of the device, the address of that person's registered place of business in Great Britain has been provided to the Secretary of State by the manufacturer or the UK responsible person;

(b) that person supplies the Secretary of State with—

(i) a description of the relevant device; and

(ii) the relevant information in paragraph (4); and

(c) that person pays to the Secretary of State the relevant fee in accordance with regulation 53.**]**

[[F5](2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.**]**

(3) **[**[F6]The UK responsible person appointed in accordance with paragraph (2)(a)(ii) must—**]**

(a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;

(c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;

[[F7](d) where they have samples of the device or access to the device, comply with any request from the Secretary of State to provide such samples or access;

(e) where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the Secretary of State to provide such samples or access, and communicate to the Secretary of State whether the manufacturer intends to comply with that request;

(f) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed;

(h) if the manufacturer acts contrary to its obligations under these Regulations—

(i) terminate the legal relationship with the manufacturer; and

(ii) inform the Secretary of State and, if applicable, the relevant approved body of that termination.**]**

(4) In this regulation "relevant information" means—

(a) in relation to a new relevant device, a statement indicating that the device is a new relevant device;

(b) if the device consists wholly or partly of reagents, reagent products or calibration and control materials, appropriate information in terms of common technological characteristics and analytes;

(c) if the device does not wholly or partly consist of reagents, reagent products or calibration and control materials, the appropriate indications;

(d) in relation to devices in a list in Annex II and devices for self-testing—

(i) all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex 1;

(ii) if requested by the Secretary of State, the labelling and instructions for use for when the device is placed on the market or put into service;

(e) in relation to devices for performance evaluation which relate either to devices referred to in a list in Annex II or to devices for self-testing, all data allowing for identification of such devices, the analytical and where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex I.

(5) Within two years of the placing of a new relevant device on the market, the Secretary of State may, where the Secretary of State considers it justified, request a report relating to the experience gained with the device subsequent to it being placed on the market.

(6) In this regulation a device is a "new relevant device" if—

(a) there has been no such device continuously available on the United Kingdom **[**F8or EEA market**]** during the previous three years for the relevant analyte or other parameter; or

(b) use of the device has involved analytical technology not continuously used in connection with a given analyte or other parameter on the United Kingdom **[**F8or EEA market**]** during the previous three years.

[F9(7) In paragraph (3)—

(a) the references to "technical documentation" are to be construed in accordance with Annexes III to VIII;

(b) the references to "declaration of conformity" are to be construed in accordance with Annexes III, IV, V and VII."**]**.

[F10(4) In regulation 35 (determining compliance of in vitro diagnostic medical devices with relevant essential requirements)—

(a) in paragraph (2), omit the words from "if the device may reach a final user" to the end; and

(b) in paragraph (3) for "national standard" substitute "designated standard".**]**

[F11(4A) In regulation 36 (CE marking of *in vitro* diagnostic medical devices)—

(a) in the heading for "CE marking" substitute "UK marking";

(b) for "CE marking" each time those words occur substitute "UK marking";

(c) for each reference to "Annex X" substitute "Annex 2 of Regulation 765/2008";

(d) for "notified body" each time those words occur substitute "approved body".**]**

[F12(4B) For regulation 37 (CE marking of *in vitro* diagnostic medical devices that come within the scope of more than one Directive) substitute—

"**UK marking of in vitro diagnostic devices that come within the scope of this Part and other legislation**

37. Where a relevant device (within the meaning of this Part) comes within the scope of this Part and other product safety or health and safety legislation ("the other legislation") a person must not affix a UK marking to the device unless the relevant requirements of the other legislation are also satisfied.".**]**

[F13(5) In regulation 39 (exemptions from regulations 34, 36 and 38)—

(a) in paragraph (1)(b) omit "Directive 98/79 or";

(b) in paragraph (2) for "CE marking" substitute "UK marking";

(c) after paragraph (2) insert—

"(3) Regulations 34 and 36 do not apply where the Secretary of State directs that a relevant device, or a class of relevant devices, which meets other requirements or standards or which is marked other than with a UK marking which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 34 and 36, may be placed on the market.

(4) In paragraph (3), the Secretary of State, in determining whether a standard or requirement or marking ("the other standard") is equivalent to a standard or requirement

imposed by regulations 34 and 36, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.".**]**

[[F14](5A) In regulation 40 (procedures for affixing a CE marking to *in vitro* diagnostic medical devices)—

(a) in the heading and in each place in that regulation that "CE marking" occurs substitute "UK marking";

(b) for "his authorised representative", each time those words occur, substitute "their UK responsible person";

(c) for each reference to "Directive 98/79" substitute "this Part".**]**

[[F15](6) In regulation 41 (manufacturers etc. and conformity assessment procedures for in vitro diagnostic medical devices)—

(a) for each reference to "his authorised representative" substitute "their UK responsible person";

(b) for both references to "Directive 98/79" substitute "this Part";

(c) in paragraph (1) for "that apply to him" substitute "that apply to the manufacturer or, as the case may be, their UK responsible person";

(d) in paragraph (3)(c) for "notified bodies" substitute "approved bodies";

(e) in paragraph (5)—

(i) omit from the beginning to "established";

(ii) omit "in the United Kingdom".**]**

[[F16](7) In regulation 42 (UK notified bodies and the conformity assessment procedures for in vitro diagnostic devices)—

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

(b) in paragraph (1)—

(i) in the opening words, for "A UK notified body" substitute "An approved body";

(ii) in sub-paragraph (a) omit "in accordance with Directive 98/79";

(iii) in sub-paragraph (b) omit the words from "including in particular" to the end of that sub-paragraph (but not the "and" following it);

(iv) in sub-paragraph (c) for "his authorised representative" substitute "their UK responsible person";

(c) in paragraph (2) for "a UK notified body" substitute "an approved body";

(d) in paragraph (3)—

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

(ii) for "his authorised representative" in both places it occurs substitute "their UK responsible person".**]**

[[F17](8) In regulation 43 (devices for performance evaluation)—

(a) in the opening words, for "his authorised representative" substitute "their UK responsible person";

(b) in paragraph (b)(ii), for "the Directive" substitute "these Regulations".**]**

[[F18](9) In regulation 44 (registration of manufacturers etc. of in vitro diagnostic medical devices and devices for performance evaluation)—

(a) in paragraph (1)—

(i) in the opening words, for "Subject to paragraph (3), for" substitute "For";

(ii) in sub-paragraph (a) for "the United Kingdom" substitute "Great Britain";

(iii) in sub-paragraph (b) for—

(aa) "an authorised representative" substitute "a UK responsible person";

(bb) "that he is the authorised representative of the manufacturer" substitute "that they are the manufacturer's UK responsible person";

(iv) in sub-paragraph (c) for "Community market" in both places substitute "the United Kingdom or EEA market";

(v) in sub-paragraph (g)(ii) for "the United Kingdom" substitute "Great Britain";

(b) in paragraph (2)—

(i) in sub-paragraph (a) for "the United Kingdom" substitute "Great Britain";

(ii) in sub-paragraph (b)—

(aa) for "the United Kingdom" in both places substitute "Great Britain";

(bb) for "the Community or in a State which is a Party to an Association Agreement" substitute "the United Kingdom";

(cc) for "his authorised representative" substitute "their UK responsible person";

(c) omit paragraph (3).**]**

[[F19](10) Before the heading to Part V (notified bodies, conformity assessment bodies and marking of products) insert—

"**Obligations in Part IV which are met by complying with obligations in Directive 98/79**

44ZA.—(1) In this regulation—

(a) any reference to an Article or Annex is a reference to that Article or Annex in Directive 98/79 as amended from time to time;

(b) "Regulation 722/2012" means Commission Regulation (EU) 722/2012 as it applies in the European Union;

(c) "CE marking" means the CE marking required by Article 16 and shown in Annex X;

(d) "harmonised standard" is to be construed in accordance with Article 5.

(2) Where paragraph (3) applies regulations 34, 36(1) to (4), 37 and 40 are treated as being satisfied.

(3) This paragraph applies where, before placing a relevant device on the market, the manufacturer—

(a) ensures—

(i) that the device meets the essential requirements set out in Annex I and, where applicable, Regulation (EU) 722/2012, which apply to it; or

(ii) that paragraphs (6) and (7) apply;

(b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 9;

(c) ensures that the documentation required by the relevant conformity assessment procedure is drawn up;

(d) ensures that the technical and other relevant documentation required by a relevant conformity assessment procedure is prepared in or translated into English;

(e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedure set out in Annexes III, IV, V, VI or VII;

(f) draws up an EU Declaration of Conformity in accordance with Article 9;

(g) ensures that the declaration of conformity is prepared in or translated into English.

(4) Where paragraph (5) applies, regulation 43 is treated as being satisfied.

(5) This paragraph applies where before a relevant device intended for performance evaluation is made available in Great Britain for the purpose of a performance evaluation, the manufacturer—

(a) has supplied the relevant written notice which must be in English in the form required by Sections 1 and 2 of Annex VIII;

(b) has provided an undertaking to the Secretary of State to keep available the documentation required by Annex VIII for the period specified in Section 3 of Annex VIII;

(c) has taken all necessary measures to ensure that the manufacturing process for the device produces devices in accordance with the documentation referred to in the first paragraph of Section 3 of Annex VIII.

(6) Where paragraph (7) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirements referred to in regulation 35(3) and (4).

(7) This paragraph applies where—

(a) a relevant device conforms with a harmonised standard or part of a harmonised standard, which corresponds exactly to a designated standard or part of a designated standard; or

(b) a relevant device is in conformity with a common technical specification.

(8) For the purpose of this regulation in regulations 36(5), 51 and 61(8), each reference to "UK marking" is to be read as a reference to "CE marking".

Obligations in Part IV of these Regulations which are met by complying with obligations in Regulation (EU) 2017/746

44ZB.—(1) In this regulation—

(a) any reference to an Article or Annex is a reference to that Article or Annex in Regulation (EU) 2017/746 as it has effect in EU law;

(b) "CE marking" means the CE marking required by Article 18 and presented in Annex V;

(c) "harmonised standard" has the meaning given in Article 2(73);

(d) "sponsor" has the meaning given in Article 2(57).

(2) Where paragraph (3) applies, regulations 34, 36(1) to (4), 37 and 40 are treated as being satisfied.

(3) This paragraph applies where, before placing a relevant device on the market, the manufacturer—

(a) ensures—

(i) that the device meets the general safety and performance requirements in Annex I which apply to it; or

(ii) that paragraphs (6) and (7) apply;

(b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 48;

(c) ensures that the documentation required by the relevant conformity assessment procedure is drawn up;

(d) ensures that the technical documentation required by Annexes II and III and other relevant documentation required by the relevant conformity assessment procedure is prepared in or translated into English;

(e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedures set out in Annexes IX, X and XI;

(f) draws up an EU declaration of conformity in accordance with Article 17; and

(g) ensures that the declaration of conformity is prepared in or translated into English.

(4) Where paragraph (5) applies, regulation 43 is treated as being satisfied.

(5) This paragraph applies where, before a person supplies or makes available a device falling within Part IV for the purposes of performance evaluation, the sponsor of the performance evaluation—

(a) has been able to provide the Secretary of State with the required notice in the form of the application required by Chapter I of Annex XIV in English;

(b) has been able to provide the Secretary of State with an undertaking to keep available information contained in the application in accordance with Chapter II of Annex XIV.

(6) Where paragraph (7) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirements referred to in regulation 35(3) and (4).

(7) This paragraph applies where—

(a) a relevant device conforms with a harmonised standard or part of a harmonised standard, which corresponds exactly to a designated standard or part of a designated standard; or

(b) a relevant device is in conformity with a common technical specification.

(8) For the purpose of this regulation, in regulations 36(5), 51 and 61(8), each reference to "UK marking" is to be read as a reference to "CE marking".".**]**

Textual Amendments

F1 Reg. 6(2) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 35**

F2 Words in reg. 6(3) omitted (31.12.2020 immediately before IP completion day) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 2 para. 36(a)(i)**

F3 Words in reg. 6(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. 36(a)(ii)**

F4 Words in reg. 6(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. 36(b)**

F5 Words in reg. 6(3) inserted (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. 5**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Words in reg. 6(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. 36(c)(i)**

F7 Words in reg. 6(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. 36(c)(ii)**

F8 Words in reg. 6(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. 36(d)**

F9 Words in reg. 6(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. 36(e)**

F10 Reg. 6(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. 37**

F11 Reg. 6(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. 38**

F12 Reg. 6(4B) 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. 39**

F13 Reg. 6(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. 40**

F14 Reg. 6(5A) 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. 41**

F15 Reg. 6(6) 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. 42**

F16 Reg. 6(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. 43**

F17 Reg. 6(8) 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. 44**

F18 Reg. 6(9) 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. 45**

F19 Reg. 6(10) 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. 46**

Commencement Information

I1 Reg. 6(1)(2)(4)-(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)

I2 Reg. 6(3) in force at 1.5.2021, see reg. 1(2)(c) (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 6.