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.

(2) In regulation 33 (Scope of Part IV)—

(a) after paragraph 1(b) insert—

"(c) in vitro diagnostic medical devices and accessories to such devices placed on the market in accordance with Part IX except where the requirement to register in accordance with regulation 33A applies in respect of these devices.";

(b) after paragraph 2(b) insert—

"(c) devices that are placed on the market in accordance with Part IX except where the requirement to register in accordance with regulation 33A applies in respect of these devices.".

(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, or Part IX insofar as it applies to relevant devices, unless that person—

(a) is established in the United Kingdom; and

(b) has complied with paragraph (2).

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

(a) informs the Secretary of State of the address of their registered place of business in the United Kingdom or, if the person does not have a registered address, an address in the United Kingdom at which service of any document relating in any way to the person's placing of a relevant device on the market will be effective;

(b) if they are not the manufacturer of the relevant device, provides the Secretary of State with sufficient written evidence that they have the manufacturer's authority to place the relevant device on the market;

(c) supplies the Secretary of State with relevant information in relation to each device concerned; and

(d) pays to the Secretary of State the relevant fee in accordance with regulation 53.

(3) Where a person provides the Secretary of State with the evidence required by paragraph (2)(b), that person is to be regarded as the UK responsible person and that person 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;

(d) forward to the manufacturer any request by the Secretary of State for samples, or access to a device and ensure that the Secretary of State receives the samples or has been given access to the device;

(e) 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;

(f) 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 designated;

(g) terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the Secretary of State and, if applicable, the relevant notified 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 or other 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 or other market during the previous three years.

(7) In paragraph (3) the references to "technical documentation" and "declaration of conformity" are to be construed in accordance with the following—

(a) where this regulation applies and Part IV applies—

(i) the reference to technical documentation is to be construed in accordance with Annexes III to VIII;

(ii) the reference to the declaration of conformity is to be construed in accordance with Annexes III, IV, V and VII as applied by regulation 40;

(b) where this regulation applies and Part IX applies—

(i) the reference to technical documentation is to be construed in accordance with Schedules 18 and 19;

(ii) the reference to the declaration of conformity is to be construed in accordance with regulation 153.".

(4) In regulation 35 (Determining compliance of in vitro diagnostic medical devices with relevant essential requirements), in paragraph (2), omit the words from "if the device may reach a final user" to the end.

(5) In regulation 39 (Exemptions from regulations 34, 36 and 38), 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 CE 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.".

(6) In regulation 41 (Manufacturers etc. and conformity assessment procedures for in vitro diagnostic medical devices) in paragraph (5)—

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

(b) omit "in the United Kingdom".

(7) Omit regulation 42 (UK notified bodies and the conformity assessment procedures for in vitro diagnostic medical devices).