STATUTORY INSTRUMENTS

2019 No. 791

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

PART 1

Amendment of the 2002 Regulations

Amendment of Part III of the 2002 Regulations

5.—(1) Part III of the 2002 Regulations is amended as follows.

(2) In regulation 21(**1**) (Scope of Part III)—

(a) in paragraph (2), for "Annex I to that Directive" substitute "Part 1 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008";

(b) after paragraph (3) insert—

"(4) Except for the requirement to register in accordance with regulation 21A or 30(3) to (5), this Part does not apply to active implantable medical devices and accessories to such devices placed on the market in accordance with Part VIII.".

(3) After regulation 21 insert—

"**Registration of persons placing active implantable medical devices on the market**

21A.—(1) No person may place a relevant device on the market in accordance with this Part or Part VIII 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 the 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 place of business, an address in the United Kingdom at which service of any document relating in any way to the person's placing of the 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 written evidence that they have the manufacturer's authority to place the relevant device on the market;

(c) supplies the Secretary of State with a description of each device concerned; and

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

(**1**) Regulation 21 was amended by S.I. 2008/2936.

(3) Where a person provides the Secretary of State with the written 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 to 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 verify that the Secretary of State receives the samples or is 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 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 III applies—

(i) the reference to technical documentation is to be construed in accordance with Annex 2, 3 or 5;

(ii) the reference to the declaration of conformity is to be construed in accordance with Annexes 2,3 and 5 as applied by regulation 27;

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

(i) the reference to technical documentation is to be construed in accordance with Schedules 4 and 5;

(ii) the reference to the declaration of conformity is to be construed in accordance with regulation 84.".

(4) In regulation 23 (Determining compliance of active implantable medical devices with relevant essential requirements), in paragraph 3(b)—

(a) in sub-paragraph (i), omit "or another Community language, and";

(b) omit sub-paragraph (ii).

(5) In regulation 26 (Exemptions from regulations 22 and 24) after paragraph (3) insert—

"(4) Regulations 22 and 24 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 22 and 24, may be placed on the market.

(5) In paragraph (4), 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 22 and 24, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.".

(6) In regulation 30(**2**) omit paragraphs (4) and (5).

(7) Omit regulation 31(**3**) (UK notified bodies and the conformity assessment procedures for active implantable medical devices).

(**2**) Regulation 30 was amended by S.I. 2008/2396.
(**3**) Regulation 31 was amended by S.I. 2008/2936.