SCHEDULE 2

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

Amendment of regulation 5(3)

25. In regulation 21A as inserted by regulation 5(3)—

(a) in paragraph (1)—

(i) in the opening words, omit "or Part VIII insofar as it applies to relevant devices";

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

(b) for paragraph (2) substitute—

"(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, and 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 a description of the relevant device; and

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

(c) in paragraph (3)—

(i) for the opening words substitute—

"The UK responsible person appointed in accordance with paragraph (2)(a)(ii) must—";

(ii) for sub-paragraphs (d) to (g) substitute—

"(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.";

(d) for paragraph (4) substitute—

"(4) In this regulation—

(a) the references to "technical documentation" are to be construed in accordance with Annex 2, 3 or 5;

(b) the references to "declaration of conformity" are to be construed in accordance with Annexes 2, 3 and 5.".