SCHEDULE 1

Amendment of the Medical Devices Regulations 2002

Substitution of regulation 19

6. For regulation 19 (registration of persons placing general medical devices on the market) substitute—

"**Registration of persons placing general medical devices on the market**

19.—(1) Paragraph (2) applies—

(a) in relation to relevant devices that are neither Class I devices nor custom-made devices, to—

(i) a manufacturer with a registered place of business in Northern Ireland who, under their own name, places on the market in Northern Ireland any general medical device of any class, other than a system or procedure pack which is not CE marked;

(ii) a UK responsible person;

(iii) a manufacturer's authorised representative who has a registered place of business in Northern Ireland;

(iv) a manufacturer with a registered place of business in Great Britain whose authorised representative does not have a registered place of business in Northern Ireland;

(b) in relation to Class I devices and custom-made devices, to—

(i) a manufacturer who places a device on the Northern Ireland market and has a registered place of business in Northern Ireland;

(ii) an authorised representative with a registered place of business in Northern Ireland;

(c) to a person with a registered place of business in Northern Ireland who sterilises before use any devices designed by their manufacturer to be sterilised before use.

(2) For the purpose of enabling the Secretary of State to exercise the Secretary of State's functions under these Regulations, any person to whom this paragraph applies must—

(a) inform the Secretary of State of their address and registered place of business;

(b) supply the Secretary of State with a description of each category of device concerned;

(c) in the case of a UK responsible person, supply the Secretary of State with—

(i) written evidence that they have been appointed as a UK responsible person;

(ii) details of the person who has so appointed them; and

(iii) where the person placing the devices concerned on the market is neither the manufacturer nor the UK responsible person, the name and address of the registered place of business of the person placing the devices concerned on the market;

(d) in the case of an authorised representative, supply the Secretary of State with—

(i) written evidence that they have been designated as an authorised representative;

(ii) details of the person who has so designated them; and

(iii) where the person placing the devices concerned on the market is neither the manufacturer nor the authorised representative, the name and address of the registered place of business of the person placing the devices concerned on the market;

(e) inform the Secretary of State of any changes to the information referred to in sub-paragraphs (a) to (d) as and when such changes arise.

(3) The obligation in paragraph 2(2)(e) to inform the Secretary of State of any changes in relation to the information referred to in sub-paragraphs (2)(a) to (d) continues to apply following the passing of any of the dates specified in paragraph (4) that apply in respect of a particular case.

(4) The obligations in paragraph (2) begin to apply—

(a) in the case of a device that is a Class I device and custom-made devices, on 1st January 2021;

(b) in the case of a device that is a Class III or IIb implantable device, on 1st May 2021;

(c) in the case of a device that is a Class IIa or Class IIb non-implantable device, on 1st September 2021.

(5) A UK responsible 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) 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 notified body of that termination.

(6) In this regulation the references to "technical documentation" and "declaration of conformity" are to be construed in accordance with Directive 93/42.".