STATUTORY INSTRUMENTS

2021 No. 905

The Medical Devices (Northern Ireland Protocol) Regulations 2021

PART 2

Making available on the market and putting into service under Regulation (EU) 2017/745

Reprocessing of single-use devices

5. The reprocessing and further use of single-use devices is permitted only when it is carried out in accordance with Article 17.

Commencement Information

I1 Reg. 5 in force at 27.7.2021, see **reg. 1(2)**

Requirement on health institutions to provide information relating to implanted devices

6. A health institution which has implanted a device to which Article 18 applies, must make available to the patient in whom the device has been implanted—

(a) the implant card for the device bearing the health institution's identity, and

(b) the information provided by the manufacturer with the device pursuant to Article 18(1), by any means that allow rapid access to that information.

Commencement Information

I2 Reg. 6 in force at 27.7.2021, see **reg. 1(2)**

Registration of custom-made devices

7.—(1) A manufacturer who makes custom-made devices available on the market in Northern Ireland must register that type of device with the Secretary of State.

(2) Registration—

(a) must take place within 28 days beginning with the day on which that type of device is first made available on the market, and

(b) requires the manufacturer to submit to the Secretary of State the information specified in paragraph (3).

(3) The information to be submitted to the Secretary of State is—

(a) the name, business address and contact details of the manufacturer of the device;

(b) if an authorised representative has been designated by the manufacturer, the authorised representative's name, business address, contact details and evidence of that designation;

(c) a description of the type of device concerned.

(4) The manufacturer must ensure that the information submitted to the Secretary of State remains up to date.

(5) The fee payable to the Secretary of State for registering a device or amending the registration of a device under this regulation is **[**[F1]£240**]**.

(6) This regulation does not apply before 1st September 2021 in respect of any class IIa or class IIb non-implantable devices made available on the market by a manufacturer who is not established in the United Kingdom.

F1 Sum in reg. 7(5) substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **19**

Commencement Information

I3 Reg. 7 in force at 27.7.2021, see **reg. 1(2)**

Certificates of free sale - fee

8. A manufacturer or authorised representative who requests a certificate of free sale from the Secretary of State under Article 60(1), must pay to the Secretary of State a fee of £75.

Commencement Information

I4 Reg. 8 in force at 27.7.2021, see **reg. 1(2)**

Retention of documentation relating to conformity assessments and custom-made devices

9.—(1) The liquidator or trustee in bankruptcy of a manufacturer, or of an authorised representative, must—

(a) retain for the required period any documentation that consists of, or reasonably could consist of, information to which section 8 of Annex IX applies, and

(b) comply with any request made by the Secretary of State during the required period to provide the Secretary of State with the retained documentation.

(2) In this regulation, the required period is—

(a) in the case of information relating to an implantable device, 15 years after the last device was placed on the market, and

(b) in any other case, 10 years after the last device was placed on the market.

Commencement Information

I5 Reg. 9 in force at 27.7.2021, see **reg. 1(2)**

UK(NI) indication

10.—(1) This regulation applies if the CE marking is affixed in accordance with Article 20 on the basis of a certificate issued by a notified body established in the United Kingdom.

(2) The CE marking must be accompanied by the UK(NI) indication.

(3) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies.

(4) The manufacturer must affix the UK(NI) indication—

(a) visibly, legibly and indelibly, and

(b) before placing the device on the market or putting the device into service.

(5) A person may only make available on the market or put into service a device to which this regulation applies if the manufacturer has affixed the UK(NI) indication in accordance with this regulation.

(6) In this regulation, "the UK(NI) indication" means the marking in the form set out in Schedule 1 to the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020(**1**).

Commencement Information

I6 Reg. 10 in force at 27.7.2021, see **reg. 1(2)**

(**1**) S.I. 2020/1460.

Changes to legislation:
There are currently no known outstanding effects for the The Medical Devices (Northern Ireland Protocol) Regulations 2021, PART 2.