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

**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.

**Textual Amendments**

**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**

**I1** Reg. 7 in force at 27.7.2021, see **reg. 1(2)**

**Changes to legislation:**
There are currently no known outstanding effects for the The Medical Devices (Northern Ireland Protocol) Regulations 2021, Section 7.