STATUTORY INSTRUMENTS

2021 No. 905

The Medical Devices (Northern Ireland Protocol) Regulations 2021

PART 8

Amendment of the Medical Devices Regulations 2002

Revocation and transitional provision

32. After regulation 3 (scope), insert—

"**Revocation, transitional and saving provisions in respect of Regulation (EU) 2017/745**

3ZA.—(1) Subject to paragraph (2)—

(a) Parts 2 and 3 only apply in Northern Ireland for the purposes of regulating qualifying devices.

(b) Parts 5 to 7 only apply in Northern Ireland for the purposes of regulating qualifying devices and devices within the scope of Part 4.

(2) The following provisions continue to apply in Northern Ireland in accordance with this paragraph whether or not the device to which they apply is referred to in paragraph (1)—

(a) for the purposes of registration of medical devices and persons placing medical devices on the market in Northern Ireland—

(i) regulation 19 (registration of persons placing general medical devices on the market),

(ii) regulation 21B (registration of persons placing active implantable medical devices on the market), and

(iii) regulation 53 (fees in connection with the registration of devices and changes to registration details),

apply until the date which is 6 months after the date of publication of the notice referred to in Article 34(3) of Regulation (EU) 2017/745.

(b) Parts 5 to 7 apply for purposes related to the designation of conformity assessment bodies for the purposes of a UK mutual recognition agreement.

(3) For the purposes of paragraph (1), a device is a qualifying device if, by virtue of Article 120 of Regulation (EU) 2017/745—

(a) it may be placed on the market, put into service or made available in Northern Ireland in accordance with the requirements of Directive 93/42 or Directive 90/385, rather than Regulation (EU) 2017/745; and

(b) it is placed on the market, put into service or made available in Northern Ireland in accordance with, and subject to the requirements of and the arrangements set out in, Parts 2, 3 and 5 to 7."

Commencement Information

I1 Reg. 32 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 32.