DRAFT STATUTORY INSTRUMENTS

2021 No.

The Medical Devices (Northern Ireland Protocol) Regulations 2021

PART 1

Preliminary

Citation and commencement

1.—(1) These Regulations may be cited as the Medical Devices (Northern Ireland Protocol) Regulations 2021.

(2) These Regulations come into force on the day after the day on which they are made.

Extent and application

2.—(1) Parts 1, 4, 5, 7 and 8 extend to England and Wales, Scotland and Northern Ireland.

(2) Parts 2, 3 and 6 extend to Northern Ireland only.

(3) Any amendment made by Part 9 has the same extent as the provision amended.

(4) In Part 8—

(a) Regulations 30, and 32 to 37 apply in relation to Northern Ireland only;

(b) Regulation 31 applies in relation to Great Britain only.

Interpretation

3.—(1) In these Regulations—

"Regulation (EU) 2017/745" means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5th April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC(**1**);

"ethics committee" means a research ethics committee recognised or established by, or on behalf of, the Scottish Ministers, the Welsh Ministers, the Department of Health in Northern Ireland or the Health Research Authority(**2**).

(2) Unless otherwise defined in these Regulations, terms used have the same meaning as in Regulation (EU) 2017/745.

(3) In these Regulations a reference to—

(a) an Article is a reference to an Article of Regulation (EU) 2017/745;

(b) an Annex is a reference to an Annex to Regulation (EU) 2017/745.

(**1**) OJ No. L 117, 05.05.2017, p. 1., amended by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020, OJ No. L 130, 24.04.2020, p.18.

(**2**) The Health Research Authority is established by section 109 of the Care Act 2014 (c.23).

Scope

4. These Regulations apply to all devices to which Regulation (EU) 2017/745 applies.