STATUTORY INSTRUMENTS

2024 No. 221

The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024

PART 4

Amendments to the Medical Devices (Northern Ireland Protocol) Regulations 2021

Amendment to regulation 3 (interpretation)

29. In regulation 3—

(a) in paragraph (1)—

(i) after the definition of "Regulation (EU) 2017/745" insert—

""Regulation (EU) 2017/746" means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU;"

(ii) after the definition of "ethics committee" insert—

""Institute" means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators;

"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**).";

(b) for paragraph (2) substitute—

"(2) Unless otherwise defined in these Regulations—

(a) terms used in Parts 2 and 3 have the same meaning as in Regulation (EU) 2017/745;

(b) terms used in Parts 2A and 3A have the same meaning as in Regulation (EU) 2017/746.";

(c) for paragraph (3) substitute—

"(3) In these Regulations, a reference to an Article or an Annex is—

(a) in Parts 2 and 3, a reference to an Article or an Annex of Regulation (EU) 2017/745;

(b) in Parts 2A and 3A, a reference to an Article or an Annex of Regulation (EU) 2017/746.".

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