
DRAFT STATUTORY INSTRUMENTS

2021 No.

The Medical Devices (Northern
Ireland Protocol) Regulations 2021

PART 8

Amendment of the Medical Devices Regulations 2002

Amendment of regulation 2A (medical devices which are qualifying Northern Ireland goods)

31. In regulation 2A—

- (a) in paragraph (1)(a), after “Northern Ireland” insert “or of Regulation (EU) 2017/745”;
- (b) in paragraph (2)—
 - (i) the words from ““qualifying Northern Ireland good”” to the end become sub-paragraph (a); and
 - (ii) after that sub-paragraph insert—
 - “(b) “Regulation (EU) 2017/745” means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 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](#).”.