
STATUTORY INSTRUMENTS

2024 No. 221

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

PART 3

Amendments to secondary legislation

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

11. In regulation 2A(1)—

(a) in paragraph (1)—

(i) before “Notwithstanding” insert “Subject to paragraph (1A),”;

(ii) for sub-paragraph (a) substitute—

“(a) which meets the requirements of—

(i) these Regulations as they apply in Northern Ireland;

(ii) [Regulation \(EU\) 2017/745](#); or

(iii) [Regulation \(EU\) 2017/746](#); and”;

(b) after paragraph (1) insert—

“(1A) Before 25 July 2024, paragraph (1) only applies to a coronavirus test device that meets the requirements of [Regulation \(EU\) 2017/746](#) if the device also meets the requirements of—

(a) regulation 34A (approval requirement for coronavirus test devices); or

(b) the common specifications set out in Annex I and XIII to [Regulation \(EU\) 2022/1107](#).”.