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STATUTORY INSTRUMENTS

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**2024 No. 221**

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

PART 3

Amendments to secondary legislation

**Amendment to regulation 3ZA (revocation, transitional and saving provisions in respect of Regulation (EU) 2017/745)**

**12.** In regulation 3ZA(1)—

- (a) at the end of the heading insert “and [Regulation \(EU\) 2017/746](#)”;
- (b) for paragraph (1) substitute—

“(1) Subject to paragraph (2), Parts 2 to 7 only apply in Northern Ireland for the purpose of regulating qualifying devices.”;
- (c) in paragraph (2)—
  - (i) omit “whether or not the device to which they apply is referred to in paragraph (1)”;
  - (ii) for sub-paragraph (a) substitute—

“(a) for the purposes of the registration of medical devices (whether or not they are qualifying 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),
    - (iii) regulation 44 (registration of persons placing in vitro diagnostic medical devices on the market or for performance evaluation), and
    - (iv) regulation 53 (fees in connection with the registration of devices and changes to registration details),

only apply until the date which is 24 months after the date of publication of the notice referred to in Article 34(3) of [Regulation \(EU\) 2017/745](#);
  - (aa) regulations 34A to 34D, 38A to 38C, 39A, 56A, 59 and 61 continue to apply in relation to coronavirus test devices whether or not they are qualifying devices;”;
  - (iii) in sub-paragraph (b) after “5 to 7” insert “also”;
- (d) in paragraph (3)—

- (i) for “For the purposes of paragraph (1)” substitute “For the purposes of this regulation”;
- (ii) after “Regulation (EU) 2017/745” insert “or Article 110 of [Regulation \(EU\) 2017/746](#)”;
- (iii) in sub-paragraph (a) for the words from “Directive 93/42” to the end, substitute “Directive 90/385, Directive 93/42 or Directive 98/79, rather than [Regulation \(EU\) 2017/745](#) or [Regulation \(EU\) 2017/746](#); and”;
- (iv) in sub-paragraph (b), omit “, 3 and 5”.