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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 4

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

**Amendment to Schedule 2 (fees in connection with the designation of notified bodies)**

**43.** In Schedule 2—

- (a) the first column (application) in Table 1 (application fees) is amended as follows—
  - (i) at the end of entry 1 insert “of [Regulation \(EU\) 2017/745](#) or Article 34 of [Regulation \(EU\) 2017/746](#)”;
  - (ii) in entry 2, after “Article 38” insert “of [Regulation \(EU\) 2017/745](#) or Article 34 of [Regulation \(EU\) 2017/746](#)”;
  - (iii) at the end of entry 3 insert “of [Regulation \(EU\) 2017/745](#) or Article 40(10) of [Regulation \(EU\) 2017/746](#)”;
  - (iv) in entry 4—
    - (aa) after “Article 46(1)” insert “of [Regulation \(EU\) 2017/745](#) or Article 42(1) of [Regulation \(EU\) 2017/746](#)”;
    - (bb) after “an Annex” insert “to [Regulation \(EU\) 2017/745](#) or [Regulation \(EU\) 2017/746](#)”;
  - (v) in entry 5, after “Article 46(1)” insert “of [Regulation \(EU\) 2017/745](#) or Article 42(1) of [Regulation \(EU\) 2017/746](#)”;
- (b) the first column (activity) in Table 2 (fees for assessments and reviews) is amended as follows—
  - (i) in entry 1—
    - (aa) after “Article 39(4)” insert “of [Regulation \(EU\) 2017/745](#) or Article 35(4) of [Regulation \(EU\) 2017/746](#)”;
    - (bb) after “Article 38” insert “of [Regulation \(EU\) 2017/745](#) or Article 34 of [Regulation \(EU\) 2017/746](#)”;
    - (cc) at the end insert “of [Regulation \(EU\) 2017/745](#) or Article 40(10) of [Regulation \(EU\) 2017/746](#)”;
  - (ii) at the end of entry 2 insert “of [Regulation \(EU\) 2017/745](#) or Article 40(4) of [Regulation \(EU\) 2017/746](#)”;
  - (iii) at the end of entry 3 insert “of [Regulation \(EU\) 2017/745](#) or Article 40(5) of [Regulation \(EU\) 2017/746](#)”;
  - (iv) in entry 5—

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**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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- (aa) after “Article 44(7)” insert “of [Regulation \(EU\) 2017/745](#) or Article 40(7) of [Regulation \(EU\) 2017/746](#)”;
- (bb) in sub-paragraph (b), after “Regulation (EU) 2017/745” insert “, or [Regulation \(EU\) 2017/746](#)”.