
STATUTORY INSTRUMENTS

2023 No. 377

**The Medical Devices and Blood Safety and
Quality (Fees Amendment) Regulations 2023**

Part 4

Amendment of the Medical Devices (Northern Ireland Protocol) Regulations 2021

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

25.—(1) Schedule 2 is amended as follows.

(2) In the first column (Application) in Table 1 (Application fees)—

(a) for entry 4, substitute—

“4. For an extension of the scope of the designation under Article 46(1) which extends the body’s designation to carry out tasks included in an Annex that was not previously within the body’s designation”;

(b) after entry 4, insert—

“5. For an extension of the scope of the designation under Article 46(1) which extends the body’s designation to carry out tasks that were not previously within the scope of the body’s designation and where the Secretary of State considers that an additional assessment of the body’s procedures is required”.

(3) In the second column (Fee) in Table 1 (Application fees)—

- (a) in entry 1, for “£8,252” substitute “£35,672”,
- (b) in entry 2, for “£2,063” substitute “£8,918”,
- (c) in entry 3, for “£8,252” substitute “£35,672”,
- (d) in entry 4, for “£6,504” substitute “£12,571”, and
- (e) in entry 5, insert “£18,212”.

(4) In the second column (Fee) in Table 2 (Fees for assessments and reviews)—

- (a) in entry 1, for “£15,904” substitute “£58,341”,
- (b) in entry 2, for “£10,160” substitute “£45,675”,
- (c) in entry 3, for “£4,404” substitute “£10,072”,
- (d) in entry 4, for “£3,876” substitute “£22,789”, and
- (e) in entry 5—
 - (i) in sub-paragraph (a), for “£2,586” substitute “£18,583”, and
 - (ii) in sub-paragraph (b), for “£3,876” substitute “£22,789”.