
STATUTORY INSTRUMENTS

2023 No. 377

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

PART 2

Amendment of the Medical Devices Regulations 2002

Amendment of regulation 55 in relation to Northern Ireland (fees payable in connection with the designation etc. of conformity assessment bodies)

12.—(1) Regulation 55(1) is amended as follows.

(2) In paragraph (1)—

- (a) in sub-paragraph (a), for “£2,063” substitute “£8,918”, and
- (b) in sub-paragraph (b), for “£8,252” substitute “£35,672”.

(3) For paragraph (2), substitute—

“(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 48(4) must, in connection with that application for a variation, pay to the Secretary of State—

- (a) in respect of an extension to the scope of the body’s designation, which extends the body’s designation to carry out tasks arising out of a UK mutual recognition agreement that were not previously within the scope of the body’s designation, a fee of £12,571; or
- (b) in respect of an extension to the scope of the body’s designation, which extends the body’s designation to carry out certain tasks that were not previously within the scope of the body’s designation and which requires the Secretary of State to undertake an additional assessment of the body’s procedures, a fee of £18,212.”.

(4) In paragraph (3)—

- (a) in sub-paragraph (a), for “£15,904” substitute “£58,341”, and
- (b) in sub-paragraphs (b) and (d), for “£4,404” substitute “£10,072”.

(5) In paragraph (3A), for “£15,904” substitute “£58,341”.

(6) In paragraph (3B), for “£4,404” substitute “£10,072”.

(7) In paragraph (3D)—

- (a) in sub-paragraph (a)(i), for “£361.20” substitute “£631”, and
- (b) in sub-paragraph (a)(ii), for “£90.30” substitute “£171”.