
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 54 in relation to England, Scotland and Wales (fees payable in connection with the designation of approved bodies)

10.—(1) Regulation 54(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 45(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 to carry out tasks under Part 2, Part 3 or Part 4, which extends the body’s designation in relation to a Part under which they have already been designated, a fee of £12,571;
- (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 where the Secretary of State considers that an additional assessment of the body’s procedures is required, a fee of £18,212.”.

(4) In paragraph (3)—

- (a) in sub-paragraph (a), for “£15,904” substitute “£58,341”,
- (b) for sub-paragraph (b), substitute—

“(b) in respect of an inspection pursuant to regulation 45(7)(a), other than an initial inspection, a fee of £45,675, plus the amounts specified in paragraph (3A); and”,

- (c) in sub-paragraph (c), for “£4,404” substitute “£10,072”.

(5) In paragraph (3A)—

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

(6) In paragraph (3C)—

- (a) in sub-paragraph (a), for “£8,252” substitute “£35,672”,

- (b) in sub-paragraph (b) for “£15,904” substitute “£58,341”, and
 - (c) after sub-paragraph (b), insert “, plus the amounts specified in paragraph (3A).”.
- (7) In paragraph (3D)—
- (a) in sub-paragraph (a), for “£2,586” substitute “£18,583”,
 - (b) in sub-paragraph (b), for “£3,876” substitute “£22,789”, and
 - (c) after sub-paragraph (b), insert “, plus the amounts specified in paragraph (3A).”.
- (8) In paragraph (3E), for “£532” substitute “£1,297”.
- (9) After paragraph (3E), insert—
- “(3F) Where, pursuant to regulation 45(7)(a) or 45(7)(b), the Secretary of State conducts an on-site assessment of a subsidiary of the body, the body must pay to the Secretary of State a fee of £22,789, plus the costs and expenses referred to in paragraph (3A).”
- (10) For paragraph (5) substitute—
- “(5) In this regulation—
- “Regulation (EU) No 920/2013” means Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive [90/385/EEC](#) on active implantable medical devices and Council Directive [93/42/EEC](#) on medical devices; and
- “subsidiary” is to be construed in accordance with section 1159 of the Companies Act 2006.”.