DRAFT STATUTORY INSTRUMENTS

2023 No.

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 1 (fees for clinical investigations)

24.—(1) Schedule 1 is amended as follows.

(2) For the heading to Table 1 substitute—

"Clinical investigation of a class I device, class IIa device or class IIb device, which is neither an implantable device nor a long-term invasive device.".

(3) In the second column (Fee) in Table 1 (Clinical investigation of a class I device, class IIa device or non-invasive class IIb device)—

- (a) in entry 1, for "£3,820" substitute "£7,472", and
- (b) in entry 2, for "£2,920" substitute "£5,711".
- (4) For the heading to Table 2 substitute—

"Clinical investigation of a class IIb device, which is either an implantable device or a long-term invasive device, or a class III device.".

(5) In the second column (Fee) in Table 2 (Clinical investigation of an invasive class IIb device or class III device)—

- (a) in entry 1, for "£5,040" substitute "£15,627", and
- (b) in entry 2, for "£3,570" substitute "£11,069".