
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 regulation 16 (clinical investigation fees)

20. In regulation 16(5)—

- (a) in sub-paragraph (a), for “non-invasive class IIb device” substitute “class IIb device, which is neither an implantable device nor a long-term invasive device” and
- (b) in sub-paragraph (b), for “an invasive class IIb device or class III device” substitute “a class IIb device, which is either an implantable device or a long-term invasive device or a class III device”.