
STATUTORY INSTRUMENTS

2023 No. 627

**The Medical Devices (Amendment)
(Great Britain) Regulations 2023**

Amendments to regulation 19C (obligations in Part II and III of these Regulations which are met by complying with obligations in Regulation (EU) 2017/745)

7.—(1) Regulation 19C(1) is amended as follows.

(2) After paragraph (3)(b) insert—

“(ba) ensures that any certificate issued by a notified body in connection with that conformity assessment procedure has not expired or been withdrawn.”

(3) For paragraph (7) substitute—

“(7) This paragraph applies where, before a system or procedure pack is placed on the market, the person responsible for combining devices to produce that system or procedure pack—

- (a) has complied with the relevant requirements of Article 22 including where that Article requires a conformity assessment in accordance with Annex IX or XI; and
- (b) ensures that any certificate issued by a notified body in connection with that conformity assessment procedure has not expired or been withdrawn.”