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STATUTORY INSTRUMENTS

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**2023 No. 627**

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

**Amendments to regulation 44ZA (obligations in Part IV which are met by complying with obligations in Directive 98/79)**

- 9.—(1) Regulation 44ZA(1) is amended as follows.
- (2) In paragraph (1)(a) for “amended from time to time” substitute “it had effect on 25 May 2022”.
- (3) In paragraph (3)—
- (a) at the beginning insert “Subject to to paragraph (3A),”;
- (b) after sub-paragraph (b) insert—
- “(ba) ensures that any certificate issued by a notified body in connection with that conformity assessment procedure is valid by virtue of Article 110(2) of Regulation (EU) 2017/746;”;
- (c) in sub-paragraph (f) for “draws up” substitute “has drawn up before 26 May 2022”.
- (4) After paragraph (3) insert—
- “(3A) Paragraph (3) only applies to a relevant device for which the conformity assessment procedure under Article 9 did not require the involvement of a notified body, if the conformity assessment procedure for that device under Article 48 of Regulation (EU) 2017/746 would require the involvement of a notified body.”.