STATUTORY INSTRUMENTS

2023 No. 627

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

Amendments to regulation 19B (obligations in Part II of these Regulations which are met by complying with obligations in Directive 93/42)

6.—(1) Regulation 19B(**1**) is amended as follows.

(2) In paragraph (1)(a)—

(a) after "Directive 93/42" insert "as it had effect on 25 May 2021";

(b) omit "as amended from time to time".

(3) In paragraph (3)—

(a) at the beginning insert "Subject 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 120(2) of Regulation (EU) 2017/745;";

(c) in sub-paragraph (f) for "draws up" substitute "has drawn up before 26 May 2021".

(4) After paragraph (3) insert—

"(3A) Paragraph (3) only applies to a class I device under the Directive if—

(a) the conformity assessment procedure under Article 11 required the involvement of a notified body; or

(b) the conformity assessment procedure for that device under Article 52 of Regulation (EU) 2017/745 would require the involvement of a notified body (if it were to be assessed under that regulation).".

(5) In paragraph (7)—

(a) after sub-paragraph (b) insert—

"(ba) ensures that any certificate in relation to the system or procedure pack or a device within it that was issued by a notified body under the Directive is valid by virtue of Article 120(2) of Regulation (EU) 2017/745;

(bb) ensures that the declarations required by Article 12 were drawn up before 26 May 2021;";

(b) at the end of sub-paragraph (c) omit "and";

(c) at the end of sub-paragraph (d) for "English." substitute "English; and";

(d) after sub-paragraph (d) insert—

"(e) ensures that the system or procedure pack does not contain a class I device under the Directive for which—

(**1**) Regulation 19B was inserted by S.I. 2019/791.

(i) the conformity assessment procedure under Article 11 did not require the involvement of a notified body; and

(ii) the conformity assessment procedure under Article 52 of Regulation (EU) 2017/745 would not require the involvement of a notifed body (if it were to be assessed under that regulation).”.