Draft Regulations laid before Parliament under section 47(3) and (6)(a) of the Medicines and Medical Devices Act 2021, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2023 No.

MEDICAL DEVICES

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

Made - - - -	***
Coming into force	
Regulations 1 to 4	*30th June 2023*
Remainder	*1st July 2023*

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 15(1), 16(1)(a), (b), (d) to (g) and (i), 17(1)(b) and (c), and 43(2) of the Medicines and Medical Devices Act 2021(**1**), after having considered the matters set out in section 15(2) to (4) of that Act.

The Secretary of State has carried out a public consultation in accordance with section 45(1) of that Act.

In accordance with section 47(3) and (6)(a) of that Act, a draft of this instrument has been laid before and approved by a resolution of each House of Parliament.

Citation, extent and application

1.—(1) These Regulations may be cited as the Medical Devices (Amendment) (Great Britain) Regulations 2023.

(2) These Regulations extend to England and Wales, Scotland, and Northern Ireland.

(3) These Regulations apply in relation to Great Britain.

Commencement

2.—(1) Regulations 1 to 4 come into force on 30th June 2023.

(2) Regulations 5 to 10 come into force on 1st July 2023.

(**1**) 2021 c. 3. Section 17 was amended by S.I. 2021/905. There are other amendments to the Act not relevant to these Regulations.

Amendments to the Medical Devices Regulations 2002

3. The Medical Devices Regulations 2002(**2**) are amended in accordance with regulations 4 to 10.

Amendments to regulation 1ZA (expiry of certain provisions in these Regulations)

4. For regulation 1ZA(**3**), substitute—

"**1ZA.**—(1) Subject to paragraph (3), regulations 19B and 30A cease to have effect at 23:59 on 30 June 2028.

(2) Subject to paragraph (3), regulations 19C, 44ZA and 44ZB cease to have effect at 23:59 on 30 June 2030.

(3) The following cease to have effect at 23:59 on 30 June 2023—

(a) regulation 19B(4), (5), (8) and (9);

(b) regulation 19C(8) and (9);

(c) regulation 30A(4) to (7);

(d) regulation 44ZA(4) and (5);

(e) regulation 44ZB(4) and (5).".

Amendments to regulation 2 (interpretation)

5. In regulation 2(1)(**4**) after the definition of "Regulation (EU) No 722/2012" insert—

""Regulation (EU) 2017/745" means Regulation (EU) 2017/745(**5**) of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;

"Regulation (EU) 2017/746" means Regulation (EU) 2017/746(**6**) of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU;".

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(**7**) 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;";

(**2**) S.I. 2002/618.
(**3**) Regulation 1ZA was inserted by S.I. 2019/791.
(**4**) Relevant amending instruments are S.I. 2013/2327, 2021/873.
(**5**) OJ No. L 117, 5.5.2017, p.1; amended by OJ No. L130, 24.4.2020, p.18 and OJ No. L80, 20.03.2023, p.24.
(**6**) OJ No. L 117, 5.5.2017, p.176; amended by OJ No. L19, 28.1.2022, p.3 and OJ No. L80, 20.03.2023, p.24.
(**7**) Regulation 19B was inserted by S.I. 2019/791.

(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—

(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).".

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(**8**) 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.".

(**8**) Regulation 19C was inserted by S.I. 2019/791.

Amendments to regulation 30A (obligations in Part III which are met by complying with obligations in Directive 90/385)

8.—(1) Regulation 30A(**9**) is amended as follows.

(2) In paragraph (1)(a)—

(a) after "Directive 90/385" insert "as it had effect on 25 May 2021";

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

(3) In paragraph (3)—

(a) after sub-paragraph (b) insert—

"(ba) ensures that the 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;";

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

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

9.—(1) Regulation 44ZA(**10**) 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.".

Amendments to regulation 44ZB (obligations in Part IV of these Regulations which are met by complying with obligations in Regulation (EU) 2017/746)

10. In regulation 44ZB(**11**), 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;".

(**9**) Regulation 30A was inserted by S.I. 2019/791.
(**10**) Regulation 44ZA was inserted by S.I. 2019/791.
(**11**) Regulation 44ZB was inserted by S.I. 2019/791.

Name
Address — Parliamentary Under Secretary of State
Date — Department of Health and Social Care

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medical Devices Regulations 2002 (S.I 2002/618) ("the 2002 Regulations") to extend the periods for which certain medical devices that comply with EU legislation can be placed on the market in Great Britain. The 2002 Regulations were made under section 2(2) of the European Communities Act 1972, the Consumer Protection Act 1987 and the Finance Act 1973, and implemented Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC.

Regulation 4 substitutes regulation 1ZA of the 2002 Regulations. Regulation 1ZA makes provision for when regulations 19B, 19C, 30A, 44ZA and 44ZB will cease to have effect. The new regulation 1ZA sets out different dates ranging from 30 June 2023 to 30 June 2030. The effect of these new dates is that the period for placing devices on the market in Great Britain under regulations 19B and 30A (except custom-made devices), and 19C, 44ZA and 44ZB is extended.

Regulations 6 to 10 amend regulations 19B, 19C, 30A, 44ZA and 44ZB to make it clear that the manufacturer must ensure the certificate of conformity (if there is one) for the relevant device is valid before placing the device on the market. The amendments to regulations 19B, 30A and 44ZA provide that certificates issued under Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC that remain valid by virtue of the transitional provisions in Regulation (EU) 2017/745 or Regulation (EU) 2017/746, are considered valid for placing devices on the market in accordance with regulations 19B, 30A and 44ZA.

Regulations 6, 8, and 9 amend regulations 19B, 30A and 44ZA to provide that references to the relevant EU directive are references to that directive before it was repealed and the declaration of conformity must have been drawn up in accordance with those directives before they were repealed.

Regulations 6 and 9 insert new paragraphs in regulations 19B and 44ZA to exclude from their scope devices for which the conformity assessment under the relevant EU directive did not require the involvement of a notified body and for which the conformity assessment under the relevant EU regulation would also not require the involvement of a notified body (if it were assessed under that regulation). This reflects the transitional provisions in Regulation (EU) 2017/745 and Regulation (EU) 2017/746 that mean these devices can also no longer be placed on the EU market.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen. The explanatory memorandum is published alongside this instrument at www.legislation.gov.uk.