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

2025 No.

MEDICAL DEVICES

The Medical Devices (Amendment) (Great Britain) Regulations 2025

Made - - - -	*****
Coming into force - -	*24th May 2025*

The Secretary of State in exercise of powers conferred by sections 15(1), 16(1)(a), (b), (c), (e), (g) and (i),17(1)(b) and (c) of the Medicines and Medical Devices Act 2021(**1**) makes these regulations.

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

In accordance with section 15(2) to (4) of that Act, the Secretary of State's overarching objective in making these Regulations is safeguarding public health, the Secretary of State has had regard to the matters specified in section 15(3) of that Act, and the Secretary of State considers that, where these Regulations may have an impact on the safety of medical devices, the benefits of making these Regulations outweigh the risks.

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, commencement, extent and application

1.—(1) These Regulations may be cited as the Medical Devices (Amendment) (Great Britain) Regulations 2025.

(2) These Regulations come into force on 24th May 2025.

(3) These Regulations extend to England and Wales, Scotland and Northern Ireland, and apply in relation to England, Wales and Scotland only.

Amendment to the Medical Devices Regulations 2002

2.—(1) The Medical Devices Regulations 2002(**2**) are amended as follows.

(2) Omit—

(**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.
(**2**) S.I. 2002/618.

(a) regulation 4H(**3**) (revocation of Commission Decision 2002/364 on 26th May 2025 and its effect before that date),

(b) regulation 4J(**4**) (revocation of Commission Regulation (EU) No 207/2012 on 26th May 2025),

(c) regulation 4K(**5**) (revocation of Regulation (EU) No 722/2012 on 26th May 2025) and

(d) regulation 4L(**6**) (revocation of Regulation (EU) No 920/2013 on 26th May 2025 and its effect before that date).”

Name
Parliamentary Under Secretary of State
Department of Health and Social Care

Address
Date

(**3**) Regulation 4H was inserted by S.I. 2019/791 and amended by 2021/873.
(**4**) Regulation 4J was inserted by S.I. 2019/791 and substituted by S.I. 2021/873.
(**5**) Regulation 4K was inserted by S.I. 2019/791 and substituted by S.I. 2021/873.
(**6**) Regulation 4L was inserted by S.I. 2019/791 and amended by 2021/873.

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") by removing the 25th and 26th May 2025 revocation dates of the following pieces of assimilated EU law:

- Commission Decision 2002/364 (on common technical specifications for in vitro medical devices),
- Commission Regulation (EU) No 207/2012 (on electronic instructions for use of medical devices),
- Regulation (EU) No 722/2012 (concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin) and
- Regulation (EU) No 920/2013 (on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices).

The 2002 Regulations were made under section 2(2) of the European Communities Act 1972 to implement Directives 90/385/EEC, 93/42/EEC and 98/79/EC.

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