Draft Regulations laid before Parliament under section 47(3), (4) and (6)(a) of the Medicines and Medical Devices Act 2021 (c. 3) and paragraphs 8F(1) and (2)(c) and 12(1) of Schedule 7 to the European Union (Withdrawal) Act 2018 (c. 16), for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2026 No.

MEDICAL DEVICES

FEES AND CHARGES

The Medical Devices (Fees Amendment) Regulations 2026

Made - - - -	***
Coming into force - -	*1st April 2026*

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8C(1)(a) and (c) of, and paragraph 1(1)(ab)(**a**) of Schedule 4 to, the European Union (Withdrawal) Act 2018(**b**), and sections 15(1), 16(1)(a)(ii) and (2), 17(1)(a) and 43 of the Medicines and Medical Devices Act 2021(**c**).

The Secretary of State has carried out a public consultation in accordance with section 45(1) of the Medicines and Medical Devices Act 2021.

In accordance with section 15(2) to (4) of the Medicines and Medical Devices Act 2021, the Secretary of State's overarching objective in making these Regulations is safeguarding public health, and 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), (4) and (6)(a) of the Medicines and Medical Devices Act 2021 and paragraphs 8F(1) and (2)(c)(**d**) and 12(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, a draft of this instrument has been laid before and approved by a resolution of each House of Parliament.

(**a**) The powers in paragraph 1(1)(ab) of Schedule 4 to the European Union (Withdrawal) Act 2018 are exercisable by the "appropriate authority". See paragraph 2 of that Schedule, which defines "appropriate authority" for the purposes of paragraph 1 of that Schedule.

(**b**) 2018 c. 16. The European Union (Withdrawal) Act 2018 was amended by the European Union (Withdrawal Agreement) Act 2020 (c. 1) ("the 2020 Act"). Section 8C was inserted by section 21 of the 2020 Act, and paragraph 1(1)(ab) of Schedule 4 by section 28(a) of the 2020 Act.

(**c**) 2021 c. 3. The Medicines and Medical Devices Act 2021 was amended by the Health and Care Act 2022 (c. 31) and S.I. 2021/905.

(**d**) Paragraph 8F was inserted by paragraph 51 of Schedule 5 to the 2020 Act.

The Treasury have consented to the making of these Regulations as required by paragraph 3(1) of Schedule 4 to the European Union (Withdrawal) Act 2018.

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Medical Devices (Fees Amendment) Regulations 2026.

(2) These Regulations come into force on 1st April 2026.

(3) Any amendment made by these Regulations has the same extent and application as the provision amended, subject to paragraph (4).

(4) In these Regulations—

(a) regulation 3 applies in relation to England and Wales and Scotland;

(b) regulation 4 applies in relation to Northern Ireland.

Amendment of the Medical Devices Regulations 2002

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

Amendment of regulation 53 in relation to England and Wales and Scotland

3. In regulation 53 (fees in connection with the registration of devices and changes to registration details)(**b**)—

(a) the existing text becomes paragraph (1);

(b) in that paragraph, for "£261" substitute "£300";

(c) after that paragraph, insert—

"(2) Any person who has a registration in accordance with regulation 7A, 19, 21A, 33A or 44 shall, in respect of the maintenance of that registration by the Secretary of State, pay to the Secretary of State an annual fee of £300 for each device registered and that fee—

(a) shall be payable for each fee period during which the registration is maintained, starting with the fee period immediately following that in which the person paid the fee for the device registration in accordance with paragraph (1); and

(b) shall be due on the first day of each fee period in relation to which a fee is payable.

(3) Where a person is liable to pay a fee under this regulation in respect of a device, no fee is payable under this regulation for an additional device which has the same registration category (whether registered simultaneously or subsequently, and whether the additional device also has other registration categories or not).

(4) Where a person supplies information referred to in paragraph (1) after the first day of a fee period, then the amount of the fee due in accordance with paragraph (1) shall be adjusted, pro rata, starting with the day on which the information is supplied, in accordance with the remaining number of days in the fee period.

(5) A person may not place a device on the market unless they have paid all fees for which they are liable under this regulation, whether or not those fees relate to that device.

(**a**) S.I. 2002/618; relevant amending instruments are S.I. 2019/791, 2020/1478, 2023/377, and 2025/749.
(**b**) Amended by S.I. 2019/791, 2023/377, and 2025/749.

(6) Where a person has registered a device under this regulation prior to 1st April 2026, the first fee period for which a fee is payable under paragraph (2) begins on 1st April 2026 and ends on 31st March 2027.

(7) In this regulation—

"fee period" means the period beginning with 1st April in any year and ending with 31st March in the following year;

"Global Medical Device Nomenclature" means the standard for the naming and categorisation of medical devices as maintained by the GMDN Agency, a company with registered company number 05392271, or any successor to that company;

"maintenance", in relation to a registration, includes—

(a) holding information supplied in relation to a registration;

(b) regulatory oversight by the Secretary of State;

(c) monitoring, identification, and addressing of safety issues by the Secretary of State in relation to the device registered.

"registration category" means, in accordance with the Global Medical Device Nomenclature as at the first day of the relevant fee period—

(a) a Level 2 Category; or

(b) where there is no applicable category under sub-paragraph (a), a Level 1 Category.".

Amendment of regulation 53 in relation to Northern Ireland

4. In regulation 53 (fees in connection with the registration of devices and changes to registration details)(**a**)—

(a) the existing text becomes paragraph (1);

(b) in that paragraph, for "£261" substitute "£300";

(c) after that paragraph, insert—

"(2) Any person who has a registration in accordance with regulation 19, 21B, or 44 shall, in respect of the maintenance of that registration by the Secretary of State, pay to the Secretary of State an annual fee of £300 for each device registered and that fee—

(a) shall be payable for each fee period during which the registration is maintained, starting with the fee period immediately following that in which the person paid the fee for the device registration in accordance with paragraph (1); and

(b) shall be due on the first day of each fee period in relation to which a fee is payable.

(3) Where a person is liable to pay a fee under this regulation in respect of a device, no fee is payable under this regulation for an additional device which has the same registration category (whether registered simultaneously or subsequently, and whether the additional device also has other applicable registration categories or not).

(4) Where a person supplies information referred to in paragraph (1) after the first day of a fee period, then the amount of the fee due in accordance with paragraph (1) shall be adjusted, pro rata, starting with the day on which the information is supplied, in accordance with the remaining number of days in the fee period.

(**a**) Amended by S.I. 2020/1478, 2023/377, and 2025/749.

(5) A person may not place a device on the market unless they have paid all fees for which they are liable under this regulation, whether or not those fees relate to that device.

(6) Where a person has registered a device under this regulation prior to 1st April 2026, the first fee period for which a fee is payable under paragraph (2) begins on 1st April 2026 and ends on 31st March 2027.

(7) In this regulation—

"fee period" means the period beginning with 1st April in any year and ending with 31st March in the following year;

"Global Medical Device Nomenclature" means the standard for the naming and categorisation of medical devices as maintained by the GMDN Agency, a company with registered company number 05392271, or any successor to that company;

"maintenance", in relation to a registration, includes—

(a) holding information supplied in relation to a registration;

(b) regulatory oversight by the Secretary of State;

(c) monitoring, identification, and addressing of safety issues by the Secretary of State in relation to the device registered.

"registration category" means, in accordance with the Global Medical Device Nomenclature as at the first day of the relevant fee period—

(a) a Level 2 Category; or

(b) where there is no applicable category under sub-paragraph (a), a Level 1 Category.".

Amendment of the Medical Devices (Northern Ireland Protocol) Regulations 2021

5.—(1) The Medical Devices (Northern Ireland Protocol) Regulations 2021(**a**) are amended as follows.

(2) In regulation 7 (registration of custom-made devices)(**b**)—

(a) in paragraph (5), for "£261" substitute "£300";

(b) after paragraph (5), insert—

"(5A) Any person who has a registration in accordance with this regulation shall, in respect of the maintenance of that registration by the Secretary of State, pay to the Secretary of State an annual fee of £300 for each device registered, and that fee—

(a) shall be payable for each fee period during which the registration is maintained, starting with the fee period immediately following that in which the person paid the fee for the device registration in accordance with paragraph (5); and

(b) shall be due on the first day of each fee period in relation to which a fee is payable.

(5B) Where a person is liable to pay a fee under this regulation in respect of a device, no fee is payable under this regulation for an additional device which has the same registration category (whether registered simultaneously or subsequently, and whether the additional device also has other registration categories or not).

(5C) Where a person registers a device under this regulation after the first day of a fee period, then the amount of the fee due in accordance with paragraph (5) shall be adjusted,

(**a**) S.I. 2021/905; relevant amending instruments are S.I. 2023/377 and 2025/749.
(**b**) Amended by S.I. 2023/377 and 2025/749.

pro rata, starting with the day on which the information is supplied, in accordance with the remaining number of days in the fee period.

(5D) A person may not place a device on the market unless they have paid all fees for which they are liable under this regulation, whether or not those fees relate to that device.

(5E) Where a person has registered a device under this regulation prior to 1st April 2026, the first fee period for which a fee is payable under paragraph (5A) begins on 1st April 2026 and ends on 31st March 2027.

(5F) In this regulation—

"fee period" means the period beginning with 1st April in any year and ending with 31st March in the following year;

"Global Medical Device Nomenclature" means the standard for the naming and categorisation of medical devices as maintained by the GMDN Agency, a company with registered company number 05392271, or any successor to that company;

"maintenance", in relation to a registration, includes—

(a) holding information supplied in relation to a registration;

(b) regulatory oversight by the Secretary of State;

(c) monitoring, identification, and addressing of safety issues by the Secretary of State in relation to the device registered.

"registration category" means, in accordance with the Global Medical Device Nomenclature as at the first day of the relevant fee period—

(a) a Level 2 Category; or

(b) where there is no applicable category under sub-paragraph (a), a Level 1 Category.".

Signed by the authority of the Secretary of State for Health and Social Care

Name
Minister of State
Date Department of Health and Social Care

We consent

Name
Name
Date Two of the Lords Commissioners of His Majesty's Treasury

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the Medical Devices Regulations 2002 ("the 2002 Regulations") and the Medical Devices (Northern Ireland Protocol) Regulations 2021 ("the 2021 Regulations").

These Regulations introduce a new annual registration fee structure, where the fee is based on the number of Global Medical Device Nomenclature ("GMDN") categories which apply to the devices the manufacturer has registered with the Secretary of State. The GMDN system codifies medical devices by categorising them into five levels of increasing granularity. The references to Level 1 and Level 2 Categories are to the first two of these levels. This follows a consultation document issued by the Medicines and Healthcare products Regulatory Agency ("MHRA") on 29 August 2024. A summary of the consultation responses and the Government's response and further response to the consultation are published on the MHRA's website (www.gov.uk/government/consultations/mhra-consultation-on-statutory-fees-proposals-on-ongoing-cost-recovery).

Regulations 3 and 4 amend the 2002 Regulations to introduce the new fee structure for devices registered pursuant to the 2002 Regulations. Regulation 5 amends the 2021 Regulations to introduce the new fee structure for custom-made devices registered pursuant to the 2021 Regulations.

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. A de minimis impact assessment is available from the Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London, E14 4PU.

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ISBN 978-0-34-827773-9

£6.40

http://www.legislation.gov.uk/id/ukdsi/2026/9780348277739

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