Medicines & Healthcare products Regulatory Agency

Guidance: Preparing for the implementation and management of the device registration fee

Published February 2026

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New Device Registration Fee Regulations and Guidance

The Medicines and Healthcare products Regulatory Agency (MHRA) held a public consultation on the uplift of our fees for 2025-2027 from 29 August 2024 to 24 October 2024. This was held jointly with the Department of Health in Northern Ireland, in accordance with Section 45(1) of the Medicines and Medical Devices Act 2021. Further information on the consultation can be found at MHRA consultation on statutory fees - proposals on ongoing cost recovery.

From 1 April 2026, Regulation 53 of the UK Medical Devices Regulations 2002 (SI 618, as amended) and Regulation 7 (5) of the Northern Ireland Regulations 2021 will introduce a new annual fee and updated fee structure. This guidance explains how the new fee will work and helps you prepare for its implementation.

Rationale for the new fee and changes to existing charges

Strengthening safety and supporting innovation

We have strengthened our safety and surveillance system for medical devices following the post-market surveillance legislation (SI 2024 No.1368) that came into force on 16 June 2025.

This legislation improves patient safety and enhances our ability to respond quickly to performance and safety signals. It also supports a more risk-proportionate, pro-innovation approach to regulation, as outlined in the NHS 10-year plan.

To ensure we can deliver this strengthened regulatory function effectively, we are introducing a new annual fee and updating our fee structure to provide sustainable funding.

Summary of key changes to fees and charges

- **New annual fee:** This replaces the current one-off application fee and supports ongoing surveillance and regulatory activity.

- **Letters of Designation:** From 1 April 2026, UK Responsible Persons (UKRPs) and Northern Ireland Authorised Representatives will no longer need to pay a separate fee to upload new Letters of Designation for their represented manufacturers. The current statutory fee will apply until 31 March 2026.

- **Updates to organisation name and/or address**: From 1 April 2026, you will no longer need to pay a fee to update your organisation's name or address. The current statutory fee will apply until 31 March 2026.

Fee waivers

- The MHRA will not offer waivers, SME rates, instalments, or payment plans. Fees must follow HMT's *Managing Public Money* principles, meaning they must be cost-recovery based and cannot shift costs between companies.

- The annual charge is set per chargeable GMDN® level 2 category, which already results in lower fees for SMEs. Strengthening PMS will also benefit SMEs by enabling earlier issue identification and supporting a more predictable, risk-proportionate regulatory environment.

- To ensure you are only charged for devices you manufacture and place on the market, please follow the instructions in this guidance.

New fee structure

How the new fee structure works

From 1 April 2026, the new fee will be calculated based on the Device Function GMDN® Level 2 Category that the device is allocated to by the GMDN Agency. Key points are as follows:

- **Single charge per GMDN® Code:** If a GMDN® Code and Term appears in multiple Level 2 Categories, you will only be charged once.
- **Minimised charges:** We will review all of your registered Level 2 Categories and ensure you are charged for the fewest possible GMDN® Categories.
- **Handling 'overlaps':** If you register a GMDN® that overlaps with an existing Category, we will charge based on the Category with the most GMDN® entries. This may result in GMDN® assignments shifting between Categories during the year to avoid any overcharging.
- **Level 1 Categories:** Some GMDN® Codes and Terms exist only at Level 1. In these cases, a single fee will apply for all GMDN® within that Level 1 Category.
- **Viewing your Categories:** From 1 April 2026, you can view your assigned GMDN® Categories by downloading the Export Devices Data to Excel File from the link on the Summary page of your DORS account.

This new fee structure will replace the current one-off application fee.

Paying for new device registrations from 1 April 2026

Fees will apply when you register devices in new chargeable GMDN® Categories. These fees are calculated **pro rata** and payable at the time of application through DORS.

To calculate the pro rata fee, DORS will divide the annual fee by 365 days and charge only for the number of days remaining until 1 April of the following year.

Registering devices in existing GMDN® Categories

- **No charge**: If you register a device in a Level 2 (or Level 1, where no Level 2 exists) GMDN® Category that you've already paid for, no additional fee will apply.

- **Chargeable**: If you unregister a device that was the **only one** in a given Category, and later register a new device in that same Category, a **pro rata fee** will apply.

To avoid unnecessary charges, **register the new device first**, then unregister the old one. If you unregister first, and the device was the only one in that Category, you may incur an additional fee.

Registering with a GMDN® that falls within multiple Level 2 GMDN® Categories

See How the new fee structure works. We will ensure that you are charged for the minimum number of Categories.

Registrations where no GMDN® Level 2 Category exists

Some GMDN® Codes and Terms are only present in a Level 1 GMDN® Category. In these cases, the MHRA will charge you a single fee for all GMDN® within that same Level 1 Category.

Ensuring you won't be overcharged

DORS will calculate the **minimum** fee payable, based on your registered GMDN® Categories. See How the new fee structure works.

Preparing for the new fee

Actions required by 30 March 2026

To support the introduction of the new fee, significant updates are being made to DORS. Our IT teams need time to implement and test these changes to makes sure everything is working as expected.

To enable the new functionality from 1 April 2026, access to DORS will be blocked from 5:00 pm on Monday 30 March 2026.

Please ensure that you complete all necessary actions as early as possible and no later than 4.59pm on 30 March 2026.

Review your device details

To ensure you are charged correctly, please review your account and all registered devices. You should:

- **unregister devices** you no longer manufacture or place on the market, have never placed on the market, have registered in error, or that do not fall within the definition of a medical device.
- **register devices** you intend to place on the market but have not yet registered.

Important notes: This is especially important for devices that you use in the manufacturing processes but are not manufactured by you.

Products that do not fall within the definition of a medical device must also be unregistered. If you are unsure if your device requires registration with MHRA please see Borderline products: how to tell if your product is a medical device.

The fee will be based on the **GMDN® Level 2 Category** (or Level 1, where no Level 2 exists) of devices registered in DORS as of **31 March 2026**, and on each subsequent year on 31 March

Check your account and contact details

Please check that your organisation name, address and contact details are correct. Updates to organisation name and/or address will incur the current statutory fee until 31 March 2026.

Make sure that the **Main Contact name and email address** listed on your account is accurate for the following account types. The MHRA will send estimated annual fee invoices to the main contact for:

- UK-based manufacturer accounts
- UK Responsible Person (UKRP) accounts
- Northern Ireland Authorised Representative accounts

Important notes:

Invoices will only be sent for manufacturer accounts with a status of **'Registered'**

UKRP and Northern Ireland Authorised Representative accounts correctly have a status of '**Not Registered**' unless they also act as a manufacturer.

Invoices for represented manufacturers will only be sent to the UKRP or Northern Ireland Authorised representative.

To update your organisation name and/or address or contact details, follow the steps in the Account Management Reference Guide and watch the video tutorial. **There is no fee to update contact details.**

Review and submit TEMP(Draft) Applications

Please review all TEMP (draft) applications and either submit them by 30 March 2026 or delete any that are no longer needed.

All TEMP applications will **be permanently removed from DORS after 5:00 pm on 30 March 2026**. Once removed these cannot be reinstated. If you need to submit an application after this date, you will need to create a new one from 1 April 2026 and pay the new fee.

Important note: Please do not wait until 30 March 2026

We strongly advise you to take action well before 30 March 2026.

Delays may result in your account being suspended or closed. DORS is expected to be busy in the lead-up to this date and you may experience delays in accessing your data.

Update your devices and product data

Please review your device data and update any obsolete GMDN® codes.

To update editable product data, such as obsolete GMDN®, market placement, end of commercial distribution date, please follow the instructions in the Device Registration Reference Guide and watch the video tutorial.

In particular we urge you to provide:

- Basic UDIs for your device
- UDI-DIs for your products (Brand/Trade name), where applicable.

These identifiers are essential for monitoring and ensuring patient safety.

Important note: Do not use the Bulk Upload templates to update product data. These templates append data rather than overwriting it, which may result in duplicate entries. You will need to remove duplicates manually.

We are working to introduce functionality that will allow you to remove more than 20 products in a single application. If system changes are implemented, we will update this section with further details.

There is no fee to add products to already registered GMDN® entries or update editable data fields via the **Update Registered Devices and Products** function**.**

Suspended accounts

Accounts with a status of "**Suspended**" on 31 March 2026 (and each subsequent year) will be **closed**. Once closed, the only available action is to unregister the account.

If your account is currently suspended because you have not renewed your registration, or the account of any represented manufacturers, follow the **Renew Registration** instructions in the Account Management Reference Guide and watch the video tutorial.

Important note: The Renew Registration function will be removed on 1 April 2026 as the annual fee will replace this process.

If you still wish to place devices on the market after 1 April 2026, you will need to:

- create a new account
- register your devices again
- pay the new fees.

Important note: Accounts with a status of **Suspended, Closed or Unregistered** do not appear on the Public Access Registration Database (PARD) and you be unable to order Certificates of Free Sale for Medical Devices.

A **Suspended**, **Closed** or **Unregistered** account means you cannot legally place devices on the UK market. It is an offence to place a non-compliant device on the market in the UK.

Unregistering Devices

To **unregister** devices you no longer manufacture or place on the market, have never manufactured, have never placed on the market, have registered in error, or that do not fall within the definition of a medical device, or any 'Pseudo' GMDN® that were migrated from our previous DORS system, follow the **Manage Registered Devices** instructions in the Device Registration Reference Guide and watch the video tutorial.

Important notes: This is especially important for devices that you use in the manufacturing processes but are not manufactured by you.

Products that do not fall within the definition of a medical device must also be unregistered. If you are unsure if your device requires registration with MHRA please see Borderline products: how to tell if your product is a medical device.

You will be charged for the Level 2 (or Level 1 where no Level 1 exists) GMDN® Category for these devices on 1 April 2026 and annually thereafter.

Incorrectly registered devices

Depending on the data field, you may be able to amend device and product details free of charge. However, not all fields can be edited after registration. Please see the **Update Registered Devices and Products** instructions in the Device Registration Reference Guide and watch the video tutorial.

- If the field cannot be updated, you must unregister and re-register the device.
- If re-registering before 30 March 2026, the current statutory fee applies.
- If re-registering on or after 1 April 2026, the new fee applies.
- No refunds will be issued for unregistered devices.
- The annual fee will be calculated on 1 April to exclude unregistered devices, only if they were the sole device in a Level 2 or Level 1 GMDN® Category.
- If other devices remain in the Category, the fee will still apply.

No longer manufacturing devices

If you no longer manufacture any devices requiring MHRA registration, follow the instructions to **Unregister Manufacturer** in the Account Management Reference Guide and watch the video tutorial.

Important note: No refunds will be issued for unregistered accounts.

Estimated annual fee calculation

Viewing your estimated annual fee

The MHRA will provide an annual fee estimate calculator on the Summary page of your DORS account so you can see your estimated fee from 1 April and until 31 March of the following year.

This will also be available on the accounts of any manufacturers you represent as a UKRP or Northern Ireland Authorised Representative.

The calculator will show the number of chargeable GMDN® Categories associated with your account.

Important note: the annual fee estimate calculator will not be available in DORS before 1 April 2026. Please see Estimated annual fee for 1 April 2026.

The estimated annual fee will update automatically when you:

- register GMDN® entries in new chargeable Categories
- unregister all GMDN® entries within a chargeable Category.

To see which chargeable GMDN® Categories you have registered, use the **Export Devices Data to Excel File** function.

Estimated annual fee for 1 April 2026

DORS will calculate the minimum fee payable. See How the new fee structure works.

The calculation will be made after **5.00 pm on 30 March** assessing your registered devices and calculating how many Level 2 (or Level 1, if applicable) GMDN® Categories they fall into. The annual fee for 1 April 2026 will be based on this calculation.

Receiving your estimated fee before 1 April 2026

As the new fee structure and annual fee estimate calculator will not be available in DORS before 1 April 2026, the MHRA will email an **estimated** annual fee to the main contact of:

- each UK-based manufacturer

UKRP or Northern Ireland Authorised Representatives Estimates will only be issued for manufacturer accounts with a status of **'Registered'**. If your account is suspended, find out how to renew your registration.

Important note: The estimate may not accurately reflect the final fee due on 1 April 2026, especially if you register or unregister devices after the estimate is generated.

Ensure that the **Main Contact** details are up to date. The MHRA will only send estimates to the main contact listed on eligible accounts.

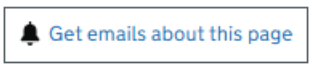
The first fee estimate emails were sent in batches in November and December 2025. A second fee estimate will be sent at the end of February 2026. Please note that this estimate may differ from the first one we sent you, even if you have not made any changes to your registration. This is because this estimate is based on the GMDN® Categories that will be used in DORS from 1 April 2026.

The GMDN® Categories are fixed for the full charging period (1 April to 31 March) of each year.

This ensures that if the GMDN Agency assigns a GMDN® to a different Category during the year, you are not charged again.

We will also publish updates to our website: Register medical devices to place on the market.

Please sign up for email notifications so that you are notified as soon as updates are published. If you haven't signed up for email updates, you will experience delays in receiving communications from MHRA, or may not receive them. The link to sign up can be found at the top and bottom of the website page:



Final fee availability

The actual annual fee payable will be available in DORS from 1 April 2026. See Paying the annual fee and Preparing for the new fee for further guidance.

Global Medical Device Nomenclature (GMDN®) and Categories

About GMDN®

“Global Medical Device Nomenclature” (GMDN®) is the globally recognised system for naming and classifying all medical devices (including implantables, medical equipment, consumables, and diagnostic devices), providing regulators, healthcare professionals, and manufacturers with a common language to communicate and share information by facilitating accurate identification, tracking, and reporting of medical devices.

About the GMDN Agency

The GMDN Agency is a registered UK charity and non-profit organisation responsible for the ongoing maintenance of the GMDN database. The latest GMDN Agency annual report is available from the Charities Commission website. For more information, please visit: https://www.gmdnagency.org/

Use of GMDN® data in DORS

The information provided in DORS includes data supplied by The GMDN Agency ('GMDN Content'), which is used under licence from The GMDN Agency. Any data/information suppliers who wish to extract GMDN Content from DORS in order to use it as a basis for creating and supporting commercial services such as alternative categorisation, mapping to other categorisations or ontologies, or for AI training purposes, must first obtain an appropriate licence from The GMDN Agency. No such activity is permitted without a licence. For more information on obtaining a licence, please contact The GMDN Agency: https://www.gmdnagency.org/contact-us/

None of the GMDN content constitutes any endorsement, advice, representation or warranty about any specific medical devices that may be described by such content; and no representation or warranty is made in relation to instructions for use, suitability for any application, treatment or condition, regulatory status, or any properties of a particular medical device.

Membership of the GMDN Agency

You do not have to subscribe to the GMDN Agency to use GMDN® for device registration in DORS. Find out more at https://www.gmdnagency.org/faqs

Understanding Level 2 GMDN® Category allocation

To view the chargeable GMDN® Category a device is assigned to, use the **Export Devices Data to Excel File** function in DORS. This functionality will be available from 1 April 2026.

Important note: GMDN® entries may move between different Level 2 Categories during charging period (1 April to 31 March of following year), to ensure you are changed for the minimum number of Categories. See How the new fee structure works.

Disagreement with the Level 2 GMDN® Category allocation

The GMDN® Categories are fixed for the full charging period (1 April to 31 March).

This ensures that if the GMDN Agency reclassifies a GMDN® Category during the year, you are not charged again.

As a result, the Category shown in DORS may differ from the one on the GMDN Agency website. Categories are reset and 'frozen' from 1 April of each year.

Unexpected number of GMDN® Categories

If more GMDN® Categories than expected appear on your account:

- check that all registered devices are correctly registered
- ensure that you manufacture the devices listed

If not, follow the **Manage Registered Devices** instructions in the Device Registration Reference Guide and watch the video tutorial to unregister any incorrect entries.

Paying the annual fee

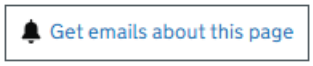
Proposed changes to DORS for fee collection

The MHRA plans to introduce a new method for collecting the annual fee in DORS.

Important note: this functionality is **still under development**, and the final process may differ.

Updates will be communicated via our website at Register medical devices to place on the market.

Please sign up for email notifications so that you are notified as soon as updates are published. The link to sign up can be found at the top and bottom of the webpage:



How to pay the annual fee

From 1 April of each year, a 'Pay annual fee' link will appear in the top right-hand corner of the Summary page of each DORS account. Click the link to access the review and payment page.

Terms of payment

- The fee must be paid in full, within 90 days from 1 April of each year.
- Instalment payments are not available.
- Failure to pay will result in your account being suspended. Read more about suspended accounts.

Organisations who are permitted to pay the fee

Only the following organisations can make payments to the MHRA:

- UK-based manufacturers
- UK Responsible Persons (UKRPs)
- Northern Ireland Authorised Representatives

UKRPs and Northern Ireland Authorised Representatives are responsible for collecting fees from their represented manufacturers and submitting payment via DORS.

Invoicing and receipts

- MHRA will **not send invoices in advance**. See viewing estimated annual fee
- Once payment is made, you will receive an **automated email** with a **paid invoice (PDF)** attached.
- You can also download a **pro forma invoice** for accounting purposes via the **'Pay annual fee'** link.

Payment methods

You can pay via:

- BACS/CHAPS
- Worldpay

Important note: All payments must be made through the DORS portal only. Do not use external MHRA payment portals.

For BACS/CHAPS payments:

- upload **proof of payment** before submitting your application.
- include the **unique reference number** from the DORS payment page in your bank's payment reference field.

Important note: Failure to include the correct reference may delay your application and result in account suspension until payment is identified.

If payment fails

If you see a **'Payment Failed'** screen in DORS and you did not cancel payment on the Worldpay screen:

- try again with a different card

Or

- contact your card issuer

Non-payment of annual fee

If payment is not made within **90 days**, your Device Registration Account will be **suspended**.

You will only be able to:

- **pay the annual fee** to reactivate the account

Or

- **unregister the account**

Important note: A suspended or unregistered account means you **cannot legally place devices on the UK market**. It is an offence to place a **non-compliant device** on the market. See: Suspended Accounts.

Suspended accounts do **not appear** on the Public Access Registration Database (PARD), and you will be **unable to order Certificates of Free Sale**.

If your account is suspended after payment

If you've paid the annual fee but your account is suspended:

1. Check your inbox (including junk/spam) for a **payment confirmation email.**
2. Confirm with your bank or card issuer that payment was made to the MHRA.
3. Email **device.registrations@mhra.gov.uk** with:
    - proof of payment
    - payment reference number
    - your Application Reference Number

To avoid issues, always pay **through the DORS portal** and include the correct **reference number** in your bank payment.

Please note: Accounts with a status of **Suspended** do not appear on the Public Access Registration Database (PARD), and you will not be able to order Certificates of Free Sale for Medical Devices.

Reminder Emails

Emails before 1 April 2026

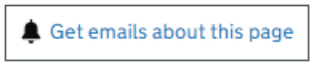
For the annual fee due on 1 April 2026, the MHRA will send email communications to the **main contact** of:

- UK-based manufacturer accounts
- UK Responsible Person (UKRP) accounts
- Northern Ireland Authorised Representative accounts for non-EU based manufacturers

These emails will include an **estimated** annual fee amount based on data in DORS before 31 March 2026.

Important note: Emails will only be sent for manufacturer accounts with a status of '**Registered**'. If your account, or the account of any manufacturer you represent as a UKRP or Northern Ireland Authorised Representative, is currently suspended, please find out how to renew your registration.

Please sign up for email notifications at Register medical devices to place on the market so that you are notified as soon as updates are published. The link to sign up can be found at the top and bottom of the webpage:



Emails after 1 April 2026

From 1 April 2027, DORS will send automated annual fee reminder emails to the main contact of eligible accounts:

- 30 days before 1 April
- 60 days before 1 April
- 90 days before 1 April

These reminders will help ensure timely payment and avoid account suspension.

Renew your registration

Renew registration until 30 March 2026

If your Device Registration account is currently **suspended** due to an incomplete **Renew Registration** application, and you wish to retain your account:

- log in to your DORS account
- review your account details and all registered devices
- register or unregister devices and products as appropriate
- unregister any **'Pseudo' GMDN®** migrated from the previous DORS system
- submit the **Renew Registration** application **before 5:00 pm on 30 March 2026**

Important note: If you do not complete this process by the deadline, your account will be **closed**. You will need to create a **new account**, re-register your devices from **1 April 2026**, and pay under the **new fee structure**.

Renew Registration from 1 April 2026

From 1 April 2026, the Renew Registration function will be removed from DORS.

Going forward you will be required to review your registration no later than 31 March of each year to ensure your account accurately reflects:

- devices you manufacture
- devices you intend to place on the UK market.

The annual fee will be calculated based on the GMDN® Level 2 Category (or Level 1, where no Level 2 exists) of devices registered in DORS as of 31 March each year.

If you do not review your registration before the annual fee is calculated on 1 April, and later unregister devices, no refunds will be issued.

Northern Ireland Fee calculation due to mandatory EUDAMED registration from 28 May 2026

From 28 May 2026, all **non-custom-made devices** manufactured by Northern Ireland-based manufacturers and represented manufacturers of Northern Ireland-based Authorised Representatives must be registered on the (European Database on Medical Devices (EUDAMED).

Only **custom-made devices** must continue be registered with MHRA per The Medical Devices (Northern Ireland Protocol) Regulations 2021

To ensure that Northern Ireland -based manufacturers and represented manufacturers of Northern Ireland-based Authorised Representatives are not charged the annual fee for devices for which registration with MHRA is not mandatory from 28 May 2026, the following fee calculations will apply:

Annual fee on 1 April 2026:

- Full fee for **custom-made** devices
- Partial fee to **27 May 2026** for **non-custom-made** devices

In year pro rata fee from 01 April 2026:

- Standard pro rata fee to **31 March 2027** for **custom-made** devices
- Partial pro rata fee to **27 May 2026** for **non-custom-made** devices

Voluntary registration of non-custom-made devices from 28 May 2026

From 28 May 2026, Northern Ireland-based manufacturers and represented manufacturers of Northern Ireland-based Authorised Representatives may choose to voluntarily register non-custom-made devices with the MHRA. Where organisations choose to do so, the fee will be payable per below:

In year pro rata fee from 28 May 2026:

Standard pro rata fee to **31 March 2027** for **non-custom-made** devices

Annual fee calculation from 01 April 2027 onwards:

The following **annual fees** will apply from **1 April 2027:**

- Full fee for **custom-made** devices (mandatory registration)
- Full fee for any **non-custom-made** devices that remain registered on the account (voluntary registration)

Contact the MHRA

If you have a query that is not answered by this guidance, please email info@mhra.gov.uk.

We are actively monitoring enquiries relating to this guidance and will update the content as needed. To help us capture and respond to questions as effectively as possible, please only contact the email address above.