Guidance

Register medical devices to place on the market

How to register your medical devices with the MHRA for the markets in Great Britain and Northern Ireland.

From: **Medicines and Healthcare products Regulatory Agency (/government/organisations/medicines-and-healthcare-products-regulatory-agency)**

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All medical devices, including in vitro devices (IVDs), custom-made devices and systems or procedure packs, must be registered with the MHRA before they can be placed on the market in Great Britain (England, Wales and Scotland).

In Great Britain devices must conform to the Medical Devices Regulations 2002 (http://www.legislation.gov.uk/uksi/2002/618/contents/made) (SI 2002 No 618, as amended) (UK MDR 2002) as they apply in Great Britain so that they can be placed on the market and registered with the MHRA.

Registration requirements differ for Northern Ireland (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#who-must-register).

The MHRA will only accept registration of devices from manufacturers or UK Responsible Persons that are based in the UK, or from Authorised Representatives based in Northern Ireland (for the purposes of the Northern Ireland market).

You must ensure all information registered with the MHRA is accurate and up to date.

Registration of your devices with the MHRA (the UK competent authority) does not represent any form of accreditation, certification, approval or endorsement by the MHRA.

Therefore, you are not permitted to make any claims to this effect, including the use of any MHRA logos in any marketing materials, on device packaging, in the instructions for use, on laboratory tickets/dockets, or in any other documentation.

If you are registering a Coronavirus (COVID-19) test kit with the MHRA, take note of our guidance for industry and manufacturers (https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work).

As part of our data validation and scrutiny of applications to register medical devices and products with the MHRA, we may request further technical

documentation from you that demonstrates your products conform to the requirements of the Medical Device Regulations. (https://www.legislation.gov.uk/uksi/2002/618/contents)

Who must register

The following requirements apply to place your device on the UK market.

Placing a device on the Great Britain market

It is a requirement of the UK MDR 2002 that you inform the MHRA before you place your device on the market in Great Britain.

You must register if you or your company sells, leases, lends or gifts:

- Class I, IIa, IIb or III devices you have manufactured
- Class I, IIa, IIb or III devices you have refurbished or re-labelled with your own name
- any system or procedure pack containing at least one medical device
- custom-made devices
- IVDs you have manufactured
- IVDs undergoing performance evaluation

Register your device to place on the Great Britain market

If the manufacturer is based outside the UK, they must appoint a single UK Responsible Person to take responsibility for all of their medical devices.

Please note that the accounts of any former Great Britain-based Authorised Representatives that have not updated their role to UK Responsible Person on the MHRA registration system, as well as the accounts of any represented manufacturers, have been suspended since 1 January 2022 until the UK Responsible Person has updated their role.

The UK Responsible Person will then assume the responsibilities of the manufacturer in terms of registering the device with the MHRA.

Where any changes to registrations are made, a statutory fee (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#fees) will apply per application.

Distributors and suppliers are not required to register with the MHRA.

In cases where the Great Britain importer is not the UK Responsible Person, the importer must inform the relevant manufacturer or UK Responsible Person of their intention to import a device.

In such cases, the UK Responsible Person or the manufacturer must provide the MHRA with the importer details, including their place of business in Great Britain.

Placing a device on the Northern Ireland market

In some circumstances, it is a requirement of the UK MDR 2002 that you inform the MHRA when you first place your device on the Northern Ireland market. The precise requirements depend on the location of the manufacturer, the location of the Authorised Representative and the device class. See below for further information.

Register your device to place on the Northern Ireland market

Requirements for non-UK manufacturers

Non-UK manufacturers are not required to appoint a UK Responsible Person for the purpose of placing medical devices on the Northern Ireland market.

Manufacturers based outside Northern Ireland or the EU are required to appoint an EU or Northern Ireland based Authorised Representative if they wish to place devices on the Northern Ireland market.

See guidance for more information about the role of the UK Responsible Person (https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#responsible).

Requirements for Great Britain-based manufacturers placing devices on the Northern Ireland market

Great Britain manufacturers must designate an Authorised Representative based in the EU or Northern Ireland in order to place a device on the Northern Ireland market.

Where an EU-based Authorised Representative is appointed, the Great Britain-based manufacturer must register all device classes other than Class I devices and general IVDs (that are not for self-testing) with the MHRA.

Where a Northern Ireland-based Authorised Representative is appointed, the Authorised Representative must register all devices with the MHRA.

Note that new requirements have been introduced regarding the registration of custom-made devices in Northern Ireland

(https://www.legislation.gov.uk/uksi/2021/905/contents/made). See below for further information.

Distributors and suppliers are not required to register with the MHRA.

Registration of importers
The Northern Ireland-based Authorised Representative must provide the MHRA with details of the person placing the product on the Northern Ireland market if the person placing the product on the market is not:

- the manufacturer, or
- the Northern Ireland-based Authorised Representative

Registration of custom-made devices in Northern Ireland
We have introduced legislation to supplement provisions that were introduced in Northern Ireland on 26 May 2021 when the EU Medical Devices Regulation (2017/745) (EU MDR) took effect (https://www.legislation.gov.uk/uksi/2021/905/contents/made). This legislation has introduced a requirement to register all custom-made devices with the MHRA within 28 days of being made available on the Northern Ireland market.

Only custom-made devices consistent with EU MDR 2017/745 can be placed on the EU market (including Northern Ireland).

Custom-made devices registered under the EU MDD or EU AIMDD and placed on the market in an EU member state other than Northern Ireland, prior to 26 May 2021, can still be registered with MHRA for the purposes of placing on the NI market only.

When you must register

When to register a device on the Great Britain market

All medical devices, including IVDs, custom-made devices and systems or procedure packs must be registered with the MHRA before they can be placed on the Great Britain market.

Custom-made devices under the EU Medical Devices Directive (EU MDD) (93/42/EEC) or EU Active Implantable Medical Devices Directive (AIMDD) (90/385/EEC) can no longer be placed on the GB market. Note that you can register your custom-made device under UK MDR 2002 Part II or Part III (which is currently consistent with EU MDD and EU AIMDD requirements) for the GB market only, with a suitable accompanying custom-made statement.

Since 1 January 2021, there have been requirements for non-UK manufacturers to have a UK Responsible Person for the purposes of registering devices placed on the Great Britain market. A Northern Ireland-based Authorised Representative can no longer register devices on a manufacturer's behalf for the Great Britain market.

Failure to register your devices will mean that you are unable to lawfully place your device on the Great Britain market.

When to register a device on the Northern Ireland market

There is currently a requirement to register certain medical devices with the MHRA (including IVDs, custom-made devices and systems and procedure packs) that are placed on the Northern Ireland market.

Only custom-made devices consistent with EU MDR 2017/745 can be placed on the EU market (including Northern Ireland).

Custom-made devices registered under the EU MDD or EU AIMDD and placed on the market in an EU member state other than Northern Ireland, before 26 May 2021, can still be registered with MHRA for the purposes of placing on the NI market only.

This requirement does not apply to manufacturers placing Class I medical devices or general IVDs (that are not for self-testing) on the Northern Ireland market in cases where:

- the manufacturer is based in the EU or EEA, or
- the manufacturer is based outside Northern Ireland, the EU or EEA and has appointed an EU-based Authorised Representative

For information on registration of custom-made devices in Northern Ireland, see above.

Information required when registering your devices with the MHRA

Provide the following information when registering your devices with us. These lists are non-exhaustive and we may request further technical documentation from you as part of our scrutiny and data validation process.

Manufacturer details:

- legal entity name and address as it appears on the device labelling/packaging
- company type (for example, limited company, sole trader)

- administrative contact (you can have up to 15 people with access)
- a letter of designation for UK Responsible Persons (where applicable)

The letter of designation for UK Responsible Persons must be a legal contract, stating that you are the exclusive UK Responsible Person acting for the manufacturer and specifying the mandatory tasks you are contracted to undertake on behalf of the manufacturer. The mandatory tasks that must appear in the designation contract can be found in our regulatory guidance for UK Responsible Persons (https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#responsible).

Device details:

- which legislation applies
- the class of device you are registering - if you are unsure of the classification and particularly if you are registering with a self-certification conformity declaration, see Borderline products: how to tell if your product is a medical device (https://www.gov.uk/guidance/borderline-products-how-to-tell-if-your-product-is-a-medical-device)
- Global Medical Devices Nomenclature (https://www.gmdnagency.org/) (GMDN)® Code and Term to describe your device
- basic UDI-DI (if applicable)
- medical device name (brand/trade/proprietary name)
- model or version detail
- catalogue/reference number
- UDI-DI (if applicable)
- UK Approved Body (or EU Notified Body) where applicable
- attributes such as sterility, contains latex, MRI compatible

You also need to provide a copy of any conformity assessment certificates or self-certification conformity declarations, as applicable.

If you do not know which GMDN® Code applies to your device, you will be able to select the relevant Term from our system. You do not need to be a member of the GMDN® Agency to find and select the appropriate GMDN® Terms in our online registration system (DORS).

However, please note that GMDN® is a worldwide system and not all of its codes and terms are considered to be medical devices in the UK. For further guidance on whether certain products are medical devices in the UK, see Borderline products: how to tell if your product is a medical device (https://www.gov.uk/guidance/borderline-products-how-to-tell-if-your-product-is-a-medical-device).

For a full view of the fields required, refer to the Manufacturer and device and product and importer attributes (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1170592/Manufacturer_and_Device_and_Product_and_Importer_Attributes_July_2023_Final.xlsx) list.

Custom-made devices

There is further information about custom-made devices. (https://www.gov.uk/government/publications/custom-made-medical-devices) This includes examples of the information we need.

If you are submitting a registration for a custom-made active implantable device, provide us with a copy of the instructions for use and the device labelling.

Custom-made devices under the EU MDD or EU AIMDD can no longer be placed on the GB or NI market. Note that you can register your custom-made device under UK MDR 2002 Part II or Part III (which is currently consistent with EU MDD or EU AIMDD requirements) for the GB market only, with a suitable accompanying custom-made statement.

Contact the MHRA by emailing Device.Registrations@mhra.gov.uk for advice on how to register your custom-made devices if:

- you are a manufacturer based outside the UK, and
- you do not have a Northern Ireland-based Authorised Representative, and
- you wish to place custom-made devices on the Northern Ireland market only

Only custom-made devices consistent with EU MDR 2017/745 can be placed on the Northern Ireland market.

Custom-made devices registered under the EU MDD or EU AIMDD and placed on the market in an EU member state other than Northern Ireland, prior to 26 May 2021, can still be registered with MHRA for the purposes of placing on the NI market only.

Systems and procedure packs

Systems and procedure packs are covered by the registration requirements set out above. You need to register if your company places on the market a system or procedure pack under your own name, and within the intended purposes and limits specified by the manufacturer, which contains devices bearing any of the following marks:

- UKCA
- CE
- CE UKNI

You need to register if your company sterilises, to place on the market under your own name, a system or procedure pack which contains devices bearing any of the following marks:

- UKCA
- CE
- CE UKNI

This is applicable to devices that are intended by the manufacturer to be sterilised before use. Manufacturers of systems and procedure packs must:

- register each system or procedure pack using GMDN
- add at least one underlying product
- upload a list of all the possible components that might be included in the system or procedure packs for that GMDN

IVDs undergoing performance evaluation

IVDs subject to new performance evaluation studies in the UK must be registered by the time the study commences.

IVDs that are subject to existing ongoing performance evaluations (commenced before 31 December 2020) must also be registered.

Non-UK manufacturers placing devices on the market for performance evaluation studies in Great Britain will require a UK Responsible Person in order to register with us.

For all performance evaluation studies, we require a Declaration for Performance Evaluation – to UK MDR 2002 Regulation 43 Statement, Annex VIII of Directive 98/79/EC, or Part A of Annex XIII of EU regulation 2017/746.

Coronavirus test device approval (CTDA) and registering with MHRA

Under regulation 34A of the Medical Devices Regulations 2002 no antigen or molecular detection COVID-19 (SARS-CoV-2) test may be placed on the UK market without first being validated against minimum performance standards through a coronavirus test device approvals desktop review.

Persons wishing to supply, put into service or place on the UK market a coronavirus test device, need to apply to the UK's Health Security Agency (UKHSA) for approval.

Registration applications for covid test devices will not be accepted by the MHRA until the devices have received CTDA or are placed onto the temporary protocol list. If you believe your Covid test device is exempt from the approval requirements and wish to register it with MHRA, it is probable you will be contacted to specify the exemption applicable under the Medical Devices Regulations 2002 (as amended by The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 (https://www.legislation.gov.uk/uksi/2021/910/contents/made) before your MHRA registration application is accepted.

For full details see For industry and manufacturers: COVID-19 tests and testing kits (https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/for-industry-and-manufactures-covid-19-tests-and-testing-kits).

Apply to register on the Device Online Registration System (DORS)

You need to create an account on the MHRA DORS (https://mhrabpm.appiancloud.com/suite/plugins/servlet/registration) before you can start registering your devices.

We will email you to confirm if your account request has been accepted or rejected.

You will not be regarded as registered with the MHRA until you have provided details of the device you are registering and have received confirmation that your device is registered. You must ensure all information registered with the MHRA is accurate and up to date. We may request additional technical documentation from you to demonstrate your products conform to the relevant regulatory requirements before your registration is confirmed.

Registration of your devices with the MHRA (the UK Competent Authority) does not represent any form of accreditation, certification, approval or endorsement by the MHRA.

Therefore, you are not permitted to make any claims to this effect, including the use of any MHRA logos in any marketing materials, on device packaging, in the instructions for use, on laboratory tickets/dockets, or in any other documentation.

If you are registering devices as a UK Responsible Person or a Northern Ireland-based Authorised Representative, you also need to provide details of the manufacturer(s) you are representing. The above device registration process will then apply.

Fees

A statutory fee (https://www.legislation.gov.uk/uksi/2002/618/regulation/53) of £240 applies for each registration application.

See Current MHRA fees (https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees) for further information on how fees are calculated and a link to the fees consultation response.

Ensure that payments for device registration applications are only made through the Device Online Registration System (DORS) (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#apply-to-register-on-the-device-online-registration-system-dors).

You can register up to 100 devices (GMDN®) with a cumulative maximum of 20,000 products (medical device brand/trade/proprietary name, model/version, catalogue/reference, UDI-DI etc.) in each application.

If you need to update or change any information in an existing registration, you may be charged a statutory fee (https://www.legislation.gov.uk/uksi/2002/618/regulation/53).

See making changes to your registration (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#making-changes-to-your-registration) for details of all chargeable changes.

Review registration

You should review your registration frequently to make sure it is up to date. It is a legal requirement to inform the MHRA of any changes to your registration per regulation 7A (general medical devices), regulation 33A (in vitro diagnostic medical devices) and regulation 21A (active implantable medical devices) of the Medical Devices Regulations (2002) (SI 2002 No 618) (as amended) concerning registration of persons placing medical devices on the Great Britain market, as and when they occur. Please do not wait for reminder emails.

We have implemented a renew registration process as a reminder to review your registration and confirm that it is up to date. The first renewal date is 1 year after account request was completed by the MHRA, and then at least every 2 years. You will receive automated email reminders 3, 2 and 1 month before your renewal date – you can review and submit the renew

registration application from 3 months before the renewal date. There is currently no fee for this application.

If you do not review your registration and submit the renew registration application your account will be suspended. Suspended accounts are removed from the Public Access Registration Database (PARD) (https://pard.mhra.gov.uk/) and you will not be able to add new devices or order certificates of free sale until you have reviewed your registration and submitted the renewal application.

Review organisation details and all registered devices and products and take the necessary action to ensure the data is correct and up to date. Follow the manage registered devices instructions in the Device registration reference guide (https://assets.publishing.service.gov.uk/media/66a8f919fc8e12ac3edb0761/Device_Registration_Reference_Guide_August_2024__Final_v1.pdf) and watch the video tutorial (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#video-tutorials) for steps on how to review your devices and take any necessary action. This includes uploading new conformity documents, adding or removing products, adding devices, or removing devices (that you no longer manufacture, or migrated devices with Pseudo Global Medical Device Nomenclature (GMDN®), where applicable).

Update any data fields that were not previously populated by following the update registered devices and products instructions in the Device registration reference guide (https://assets.publishing.service.gov.uk/media/66a8f919fc8e12ac3edb0761/Device_Registration_Reference_Guide_August_2024__Final_v1.pdf) and watch the video tutorial (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#video-tutorials). In particular we urge you to provide the UDI-DIs for your devices (where applicable) as these will be crucial for monitoring and ensuring patient safety.

If any changes need to be made to organisation details or new devices need to be added to your registration/s these are separate transactions that incur the statutory fee (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#fees) per application. Note that if your organisation name and/or address has changed you must update these before renewing your registration. You cannot do this in the renew registration application. Follow the instructions for editing organisation details in the Account management reference guide (https://assets.publishing.service.gov.uk/media/66a8f9070808eaf43b50d9f2/Account_Management_Reference_Guide_August_2024_Final_v1.pdf). The fee is payable.

If no changes need to be made, you will not currently be charged for this review. Follow the renew registration instructions in the Account management reference guide (https://assets.publishing.service.gov.uk/media/66a8f9070808eaf43b50d9f2/Account

_Management_Reference_Guide_August_2024_Final_v1.pdf) and watch the renew registration video tutorial (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#video-tutorials).

Making changes to your registration

If you are already registered with the MHRA, we encourage you to make the necessary changes to your registered information as and when they occur. Do not wait for reminder emails.

Log into MHRA DORS (https://mhrabpm.appiancloud.com/suite/) (Device Online Registration System). This is for existing customers only.

If you registered with the MHRA before 1 July 2018 and have a registration number that begins with 'CA, or IVD' or your registration does not appear on the Public Access Registration Database (PARD) (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#public-register-of-manufacturers) you will need to re-register your organisation details and devices on the DORS system.

Note that we now ask for more detailed information on your devices and products and request that you upload conformity assessment documents.

You must notify us of any changes to your registration details.

A statutory fee (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#fees) is chargeable for changes to the following:

- address
- company name
- adding devices to your registration record or the registration record of manufacturers you represent
- changing device characteristics, for example, class, from non-sterile to sterile or v.v., trade/brand name, UDIs or any field that cannot be updated in DORS – the device will need to be re-registered
- changing status of an IVD, for example a change from 'performance evaluation' to 'new' - you will need to register the IVD device again
- changing the legislation of a device (for example, from MDD/AIMD/IVDD to UK MDR 2002 part II,III or VI, or to MDR/IVDR, a new registration is required
- change of role from Authorised Representative to UK Responsible Person or vice-versa (fee chargeable per represented organisation)
- change of UK Responsible Person
- adding new/additional represented manufacturers

- uploading new letter of designation for represented manufacturers

You will not currently be charged the statutory fee for these changes:

- submitting the renew registration application
- updating contact details including email address, telephone numbers, customer service contact telephone number and/or email address
- adding products (medical device name/trade name, model/ version, catalogue/reference detail, UDI-DI, for example) to registered devices
- removing devices or products from your registration record (that you no longer manufacture, or migrated devices with Pseudo Global Medical Device Nomenclature (GMDN®), where applicable)
- updating registered device and product fields that were not populated at time of registration
- updating obsolete Global Medical Device Nomenclature (GMDN®)
- uploading and linking new conformity assessment and self-certification declaration documents to registered devices, providing the documents are consistent with the legislation that the device was originally registered under (if you wish to change the legislation, for example, from MDD/AIMD/IVDD to UK MDR 2002 part II,III or VI, or to MDR/IVDR, a new registration is required and the statutory fee will be payable)
- unregistering your account or the accounts of represented manufacturers that you no longer represent
- adding or deactivating importers

Registration of certain medical devices that have expired/expiring CE certificates

In March 2023, the EU revised the EU MDR transitional arrangements to extend the validity of EU MDD and EU AIMDD CE certificates in limited circumstances for certain medical devices. Such certificates can be relied on for placing a medical device on the Northern Ireland and Great Britain markets until the dates set out in the guidance linked below.

For more information about this, and the steps you would need to take to rely on an expired EU MDR or EU AIMD CE certificate that has been deemed valid under the EU MDR, see:

- guidance on regulation of medical devices in the UK (https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk)
- update on EU MDR revised transitional arrangements (https://www.gov.uk/government/news/impact-of-extension-of-medical-device-regulations-transitional-period-and-the-validity-of-certificates-in-the-eu)

- guidance on registration of medical devices with an expired/expiring CE certificate that is valid under EU Medical Devices Regulations (EU MDR) (https://www.gov.uk/government/publications/registration-of-reusable-or-upclassified-class-i-devices-andor-expiring-ce-certificates).

As set out in that guidance, you will need to upload a letter issued by the notified body stating the receipt of the manufacturer's application for conformity assessment and the conclusion of a written agreement. Alternatively, if you do not hold a notified body letter you will need to complete and upload the following template letter: EU MDR Article 120 Extension Confirmation Template (https://assets.publishing.service.gov.uk/media/67892d7bd0561c11b91d052a/EU_MDR_Article_120_extension_confirmation_template.docx).

Registration of certain medical devices which are EU MDD Class I reusable surgical instruments or EU MDD Class I medical devices upclassified from Class I

We have prepared guidance on registration of certain medical devices which are EU MDD Class I medical devices which are a) reusable surgical instruments or b) upclassified under EU MDR (https://www.gov.uk/government/publications/registration-of-reusable-or-upclassified-class-i-devices-andor-expiring-ce-certificates).

This contains information to be aware of if you are registering the following types of medical devices with MHRA as self-declared as meeting requirements in EU MDD:

- guidance on registration of EU MDD Class I reusable surgical instruments that would require notified body involvement in their assessment under EU MDR
- guidance on registration of EU MDD Class I medical devices that are upclassified under EU MDR

Registration of certain IVD devices that have expired/expiring CE certificates

In June 2024, the EU revised the EU IVDR transitional arrangements to extend the validity of EU IVDD CE certificates in limited circumstances for certain IVD devices. Such certificates can be relied on for placing an IVD device on the Northern Ireland and Great Britain markets until the dates set out in the guidance linked below.

For more information about this, and the steps you would need to take to rely on an expired EU IVDD CE certificate that has been deemed valid

under the EU IVDR please see the following:

- guidance on regulation of medical devices in the UK (https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk)
- guidance on registration of IVD devices with an expired/expiring CE certificate that is valid under EU IVDR (https://www.gov.uk/government/publications/registration-of-in-vitro-diagnostic-devices-with-expiring-ce-certificates)

As set out in that guidance, you will need to upload a letter issued by the notified body stating the receipt of the manufacturer's application for conformity assessment and the conclusion of a written agreement. Alternatively, if you do not hold a notified body letter you will need to complete and upload EU IVDR Article 110 Extension Confirmation Template (https://assets.publishing.service.gov.uk/media/678931202080f65f988bd321/EU_IVDR_Article_110_extension_confirmation_template.docx).

Registering IVD devices which the EU IVDR up-classifies from general IVD device

We have prepared IVD device registration guidance for information to be aware of if you are registering IVD devices that are upclassified to either a Class B, C, or D IVD device and would require notified body involvement in their assessment under EU IVDR:

- guidance on registration of EU IVDD general IVD devices that are upclassified under the EU IVDR (https://www.gov.uk/government/publications/registration-of-reusable-or-upclassified-class-i-devices-andor-expiring-ce-certificates)

Public register of manufacturers

Once registered, your company name, address and registered medical device types are added to the Public Access Registration Database (PARD) for medical device registration (https://pard.mhra.gov.uk/).

Records are listed by:

- manufacturer name
- address
- MHRA Reference (account) number
- devices registered with MHRA by medical device type (Global Medical Device Nomenclature (GMDN®) Term)
- 5-digit GMDN® code

UK Responsible Person or Northern Ireland Authorised Representative name and address is displayed within the manufacturer record (if applicable).

In vitro diagnostic medical devices registered as undergoing performance evaluation study are not published on this database.

The MHRA uses terminology to describe devices and classification per the International Medical Device Regulators Forum (IMDRF), see: Common Data Elements for Medical Device Identification (https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-rps-common-data-elements.pdf).

Brand/trade/proprietary names of registered devices are not currently displayed on PARD.

If your registration is not displaying on PARD or your devices are displaying as 'Devices pending update by manufacturer', access your account and take any necessary action to bring your registration up to date. See Review registration (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#review-registration) and Making changes to your registration (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#making-changes-to-your-registration).

Reference guides

These guides provide instructions on how to use the device registration and Certificates of Free Sale System (https://www.gov.uk/guidance/export-medical-devices-special-rules).

The screenshots in the reference guides may not exactly match the latest screens in the system. Changes will be updated in the guides as soon as possible. Always follow the system on-screen messages and information.

- Account Management Reference Guide March 2025 (https://assets.publishing.service.gov.uk/media/67c9d04175d7505462fc6698/Account_Management_Reference_Guide_March_2025_Final_v1.pdf) (PDF, 2.17 MB, 42 pages)
- Device Registration Reference Guide March 2025 (https://assets.publishing.service.gov.uk/media/67c9d05c8247839c255ae3fe/Device_Registration_Reference_Guide_March_2025__Final_v1.pdf) (PDF, 6.04 MB, 101 pages)

Video tutorials

These video tutorials show you an overview of how to use our Device Registration and Certificates of Free Sale System.

The video tutorial screens may not exactly match the latest screens in the system. Changes will be updated in the videos as soon as possible. Always follow the system on-screen messages and information.

Any fees referred to in the video tutorials are for demonstration purposes only. Refer to the Fees section (https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#fees) for current fees.

The guides below are to be viewed in conjunction with the above reference guides:

- Review page (https://mhra-gov.filecamp.com/s/mlQvl9D0d27GBF2S/fi)
- Registering a general medical device (https://mhra-gov.filecamp.com/s/6FuOxCoQTYcXFWmh/fi)
- Registering an in vitro diagnostic medical device (https://mhra-gov.filecamp.com/s/3VRv78nkUt1j2TVE/fi)
- Registering an IVD for Performance Evaluation (https://mhra-gov.filecamp.com/s/VSyR0SJ6n0kFKqmY/fi)
- Registering a custom-made medical device (https://mhra-gov.filecamp.com/s/i/OkHhSTNv1S77W9IQ)
- Registering a system or procedure pack (https://mhra-gov.filecamp.com/s/Y9OXiImIJZ0788Fw/fi)
- Using the bulk product upload template (https://mhra-gov.filecamp.com/s/TFCpKDY6mM0lScxR/fi)
- Save & exit – save draft application (https://mhra-gov.filecamp.com/s/NqOoejgMz4JZGyvH/fi)
- Making payments by BACS/CHAPS (https://mhra-gov.filecamp.com/s/Oj3jaF5ss3Meuv4r/fi)
- Making payments by worldpay (https://mhra-gov.filecamp.com/s/UUigvNA36ueUiiTF/fi)
- Updating role to UK Responsible Person (https://mhra-gov.filecamp.com/s/fOJVX2Vb2yvqVQnA/fi)
- Edit organisation details (https://mhra-gov.filecamp.com/s/EMXs2qUbh0kk1mqb/fi)
- Adding represented organisations (https://mhra-gov.filecamp.com/s/6O6SGK1YigfYRgNy/fi)
- Add importer (https://mhra-gov.filecamp.com/s/tEBZw1AuuyK2iAEP/fi)
- Deactivate importer (https://mhra-gov.filecamp.com/s/ep5sDlmPhA7Aiv0p/fi)

- Manage registered devices - Add or remove products (https://mhra-gov.filecamp.com/s/c/JRWlx6oM5M3qDilG/Ge6DBdHulv7uGQoy)
- Manage registered devices - Manage conformity documents (https://mhra-gov.filecamp.com/s/c/JRWlx6oM5M3qDilG/7K3i1iKdNO0ZFbNN)
- Manage registered devices - Deleted devices (https://mhra-gov.filecamp.com/s/c/JRWlx6oM5M3qDilG/mr7WZTwHWqHW1YDB)
- Update registered devices and update products individually (https://mhra-gov.filecamp.com/s/i/y6CHHlvP5DjqoSdJ)
- Update multiple products (https://mhra-gov.filecamp.com/s/c/JRWlx6oM5M3qDilG/FfMOubrNZ0ffAGE0)
- Resolving product data errors (https://mhra-gov.filecamp.com/s/c/JRWlx6oM5M3qDilG/Q5NBNBo94Y4p96RX)
- Update Obsolete GMDN® (https://mhra-gov.filecamp.com/s/Re6xAIE7KpBjJgXm/fi)
- Adding other addresses (Billing, manufacturing site) (https://mhra-gov.filecamp.com/s/Mozf3MR3t38S7Aw7/fi)
- Upload new Letter of Designation (https://mhra-gov.filecamp.com/s/Yaj6foQ0CI4kPhnT/fi)
- Review and renew registration (https://mhra-gov.filecamp.com/s/i/zOHhDsJ6XduQwBRa)
- Unregister manufacturer (https://mhra-gov.filecamp.com/s/7LIKsi0AeyLe869X/fi)

Contact

If you have any queries or complaints about the registration process, email device.registrations@mhra.gov.uk, quoting your reference number.

If you are already registered with us and have a question about your registration details, email device.registrations@mhra.gov.uk quoting your reference number.

If you have read the guidance on how to tell if your product is a medical device (https://www.gov.uk/guidance/borderline-products-how-to-tell-if-your-product-is-a-medical-device) and:

- are not sure whether your products qualify as medical devices, or
- are not sure which risk class applies to your medical devices

email devices.borderlines@mhra.gov.uk with the full details of your specific product for further advice.

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