Medicines & Healthcare products Regulatory Agency

Registration of medical devices

Guidance on the registration requirements for medical devices placed on the market and put into service

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Introduction and scope

This guidance has been developed to support manufacturers to determine whether their medical devices are placed on the market in or put into service in Great Britain (GB) or Northern Ireland (NI). It intends to also provide clarity on the registration requirements for these devices.

On 1 April 2026, the MHRA introduced an updated fee structure for registered medical devices in GB. This fee applies to all devices that are placed on the GB market. Refer to the Fees Guidance.

Registration requirements and the applicable fees are different for NI. Manufacturers wanting to place devices on the market in NI should follow the guidance for Northern Ireland.

Requirements in Great Britain

Under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (MDR 2002), there are two definitions that relate to the supply of devices on the GB market – “placing on the market” and “putting into service”.

As per the MDR 2002, all medical devices, including in vitro diagnostic 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 GB (i.e. England, Wales and Scotland).

Before registering devices with the MHRA, you should consider whether your device is placed on the market, put into service, or both. In most cases, a device will first be placed on the market and will subsequently be put into service when it reaches the end user and is used for its intended purpose.

If a medical device is put into service **and** placed on the market, you must register the device with the MHRA.

If a medical device is put into service only, organisations are encouraged to record this in the MHRA Device Online Registration System (DORS). If a medical device is recorded as put into service only, the MHRA DORS fee calculation process will recognise this record, and the fee will not be applied. Refer to guidance on registration for devices put into service only.

Placing on the market

Under the MDR 2002, the definition of placing on the market is as follows:

> "Placing on the market" means, in relation to a medical device, the first making available in return for payment or free of charge of a new or fully refurbished device, other than a device intended for clinical investigation, with a view to distribution, use, or both, on the Great Britain market

Before placing a device on the market in GB, it must be registered with the MHRA. This registration must also be maintained whilst the device continues to be made available on the GB market.

In most supply chains, a medical device will be placed on the market in GB at the point it is first supplied to the GB market.

Putting into service

Under the MDR 2002, the definition of putting into service is as follows:

> a) in relation to an active implantable medical device, the making available of the device to a registered medical practitioner for implantation;
>
> b) in relation to any other medical device, the first making available of the device in Great Britain to a final user, including where a device is used in a professional context for the purposes of medical analysis without being marketed

Putting into service refers to the stage at which a device is made available to the final user and is ready for its intended purpose.

There are limited scenarios where a device may be put into service without first being placed on the GB market. It may occur when a device is made and used by the manufacturer, or end user, without marketing or distribution – refer to the illustrative examples section.

Requirements in Northern Ireland

Under the terms of the Windsor Framework, the rules for placing medical devices on the NI market differ from those applicable to Great Britain (England, Wales and Scotland).

The EU Medical Device Regulation (2017/745) (EU MDR) and the In Vitro Diagnostic Medical Device Regulation (2017/746) (EU IVDR) have applied in EU member states and in Northern Ireland since 26 May 2021 and 26 May 2022 respectively.

Non-custom-made devices

From 28 May 2026, devices (other than custom-made devices) must be registered on the European Database on Medical Devices (EUDAMED) before being placed on the NI market. MHRA registration is not required from this point.

Custom-made devices

Under the Medical Devices (Northern Ireland Protocol) Regulations 2021, all manufacturers, regardless of geographical location, must register their ***custom-made devices*** with the MHRA within 28 days of the device being made available on the Northern Ireland market.

Under the EU MDR, there are three definitions that relate to the supply of devices on the NI market – "making available on the market", "placing on the market" and "putting into service".

If a custom-made device is put into service only, organisations are still encouraged to record this in the MHRA DORS. If a medical device is recorded as put into service only, the MHRA DORS fee calculation process will recognise this, and the fee will not be applicable. Refer to guidance on registration for devices put into service only.

Placing on the market

Under the EU MDR and the EU IVDR respectively, the definitions of placing on the market are as follows:

> 'placing on the market' means the first making available of a device, other than an investigational device, on the Union market;
>
> 'placing on the market' means the first making available of a device, other than a device for performance study, on the Union market;

To support implementation of these definitions, organisations should also consider the definitions of making available on the market:

> 'making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
>
> 'making available on the market' means any supply of a device, other than a device for performance study, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

In practice, organisations can consider the term making available on the market as broader than the term placing on the market in NI: 'placing on the market' only covers 'the first

making available' on the market, whereas 'making available on the market' covers any supply on the market in the course of a commercial activity.

If a custom-made device is placed on the market in NI, or made available on the market in NI, registration with the MHRA is required.

Putting into service

Under the EU MDR and the EU IVDR respectively, the definitions of putting into service are as follows:

> 'putting into service' means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;
>
> 'putting into service' means the stage at which a device, other than a device for performance study, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

Similar to the GB definition, putting into service refers to the stage at which a device is made available to the final user and is ready for its intended purpose. This could be at the end of the supply chain.

There are limited scenarios where a custom-made device may be put into service without first being placed on the NI market. It may occur when a device is made and used by the manufacturer, or end user, without marketing or distribution. To help determine if a custom-made device is put into service only in NI, refer to the illustrative examples for custom-made devices section.

Illustrative examples

The following illustrative examples have been developed to support organisations in determining the supply routes for their medical devices and the relevant registration requirements.

Note: In the following examples, Health Board/NHS Board can be used in place of NHS Trust for Wales and Scotland respectively.

Non-custom-made devices

Activity	**Registration requirements**	**Rationale**
A UK responsible person (UKRP) acts on behalf of a non-UK based manufacturer who sells devices to a GB based company. The GB based company sells these devices to customers.	The UKRP must register with the MHRA on behalf of the non-UK based manufacturer.	The non-UK based manufacturer places the devices on the market in GB.
General medical devices		
A GB based company manufactures surgical kits. These devices are provided to Hospital A.	The company must register with the MHRA.	These devices are placed on the market by the manufacturer.
A GB based company manufactures lenses. The lenses are surfaced during the manufacturing process. The manufacturer sells the lenses to another company.	The company must register with the MHRA.	This constitutes placing on the market.
A GB based manufacturer of spectacle frames intended for prescription glasses sells the spectacle frames to another company.	The company must register with the MHRA.	This constitutes placing on the market.
A manufacturer based in GB assembles lenses and spectacle frames and sells the complete glasses to another company.	The organisation must register with the MHRA	This constitutes placing on the market.
In vitro diagnostic (IVD) devices		
An NHS laboratory manufactures an IVD device. It is used the test on-site	The NHS laboratory is encouraged to	The device has been made available to the final user on

to test patients from that NHS Trust only.	register the devices and mark them as put into service only	the manufacturer's premises and has not been placed on the market. See IVD guidance.
Software as a medical device (SaMD)		
Hospital A in GB develops a software device that can only be accessed on the hospital's premises.	Hospital A is encouraged to register the device and mark it as put into service only	The device has been made available to the final user on the manufacturer's premises and has not been placed on the market.
An NHS Trust (Trust A) develops a software device that is intended to monitor patient treatment and responses. This software is provided to Trust B to use on their premises.	Trust A must register with the MHRA.	Trust A has placed the devices on the market by distributing them to Trust B.
A GB based Hospital A develops a software device that is distributed via a commercial app store.	Hospital A must register with the MHRA.	These devices are placed on the market by Hospital A.
Sterility services		
A sterile services department located in GB provides disinfection and sterilisation services to other hospitals within the same NHS Trust. This sterile services department is part of NHS Trust A. The sterile services department only provides services to other hospitals within the same NHS Trust.	The sterile service department is encouraged to register the devices and mark them as put into service only.	The sterile services department has provided services to hospitals within the same NHS Trust only. The sterile services department has put the devices into service only.
Company A is a sterile services provider located in GB. This company provides services for a range of different hospitals (both private and NHS).	The company must register with the MHRA.	This constitutes placing on the market.
A sterile services department within Hospital A manufactures a procedure pack for use within Hospital A only. Hospital A is located in GB.	The sterile service department is encouraged to register the devices and mark them as put into service only.	The sterile services department has put the devices into service only.

Custom-made devices

Activity	Registration requirements	Rationale
NHS Trust A manufactures custom-made wheelchair cushions for patients in Hospital A only.	NHS Trust A is encouraged to register the devices and mark them as put into service only.	NHS Trust A has put the device into service only.
NHS Trust A provides orthotics services for Trust B under a service level agreement (SLA). Trust A manufactures a custom-made orthotic for a patient of Trust B. The device is manufactured and fitted on Trust A premises.	NHS Trust A Hospital A is encouraged to register the devices and mark them as put into service only.	The device has been made available to the final user on the manufacturer's premises and has not been placed on the market.
NHS Trust A manufactures custom-made devices on site. These devices are also provided to Trust B. All the devices are fitted to patients on Trust B's premises.	Trust A must register with the MHRA.	Trust A has placed the devices on the market by distributing them to Trust B.
A maxillofacial department in an NHS Trust manufactures a facial prosthesis for an individual patient. The device is fitted on the same premises where it is manufactured.	The maxillofacial department is encouraged to register the devices and mark them as put into service only.	The device has been made available to the final user on the manufacturer's premises and has not been placed on the market.
A private hospital manufactures custom-made dental implants for use on their patients. The devices are used by patients of that hospital only.	The private hospital is encouraged to register the devices and mark them as put into service only.	The device has been made available to the final user on the manufacturer's premises and has not been placed on the market.
A dental laboratory manufactures custom-made implants on its premises. These implants are then sold to NHS Trust A or private dentist B for use on their patients.	The dental laboratory must register with the MHRA.	The dental laboratory has placed the devices on the market when selling and distributing these to the NHS Trust.
A company manufactures custom-made patient specific implants (PSI). NHS Trust A buys these implants from the company and fits them into their patients.	The company must register with the MHRA.	These devices are placed on the market by the company.

Registration for devices put into service only

The registration with the MHRA for devices put into service only is voluntary, and these devices are not subject to a fee.

However, post-market surveillance (PMS) is critical to ensuring that all devices continue to meet safety and performance requirements once in use. Effective PMS relies on appropriate visibility, oversight and traceability of devices across the system. For this reason, the MHRA still encourages organisations to register devices that are put into service only.

To support this, the MHRA have introduced system changes to ensure that devices identified as “put into service only” will not be charged fees, including for any new registrations of such devices. Identification of these devices in DORS will enable the MHRA to maintain oversight and support ongoing PMS activities, while ensuring that organisations are not charged incorrectly.

The MHRA therefore recommends that you review and update your registration records to clearly identify devices that are put into service only.

Important note: Specifically, for the 2026/27 fee, the MHRA will recalculate the fee estimates for any organisations who indicate on DORS that they put devices into service only. Please ensure that you follow the instructions and update your device records accordingly by **11 September 2026.** Refer to recalculating the annual fee for more information.

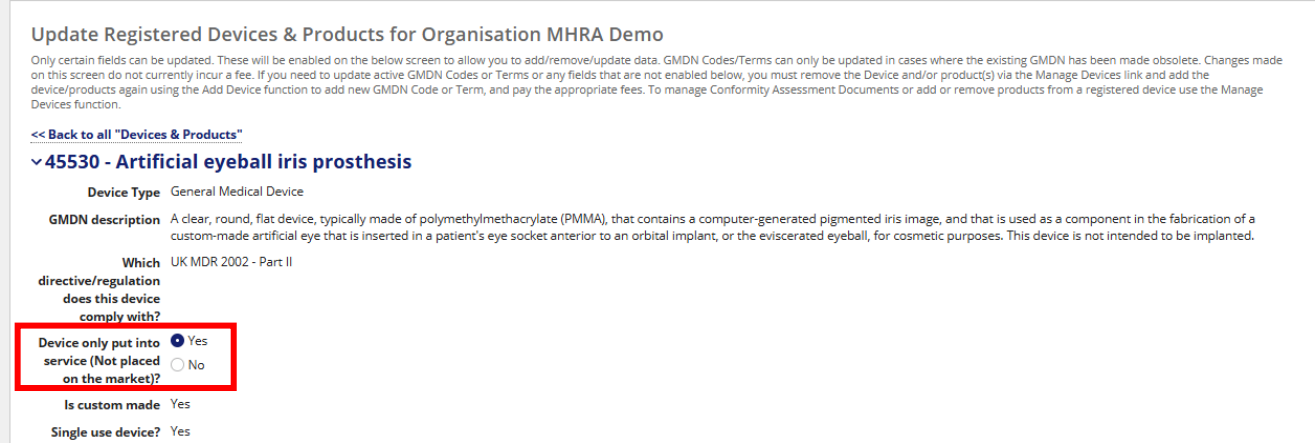
DORS functionality to identify devices put into service

Current device registrations

Once you have identified all devices that are currently registered with MHRA but that you only put into service:

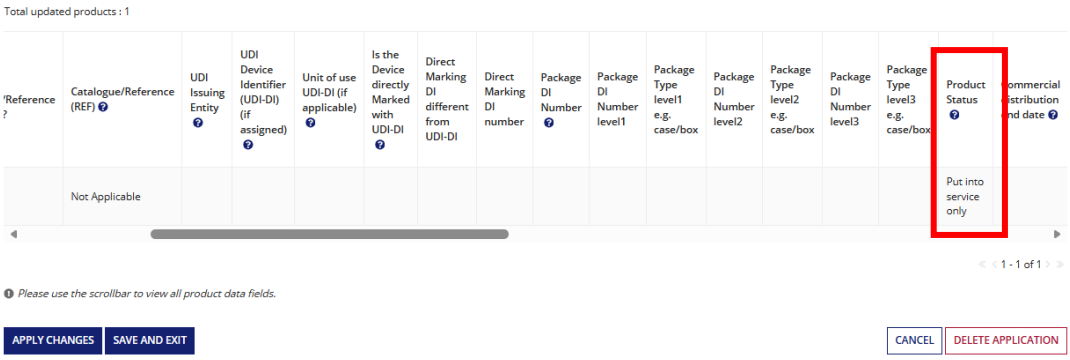
Follow the Update Registered Devices and products instructions in the Device Registration Reference Guide and select the devices you wish to update. You can only update one Device at a time.

Under the GMDN Code you will see a tick box to enable you to indicate that the device is put into service only:



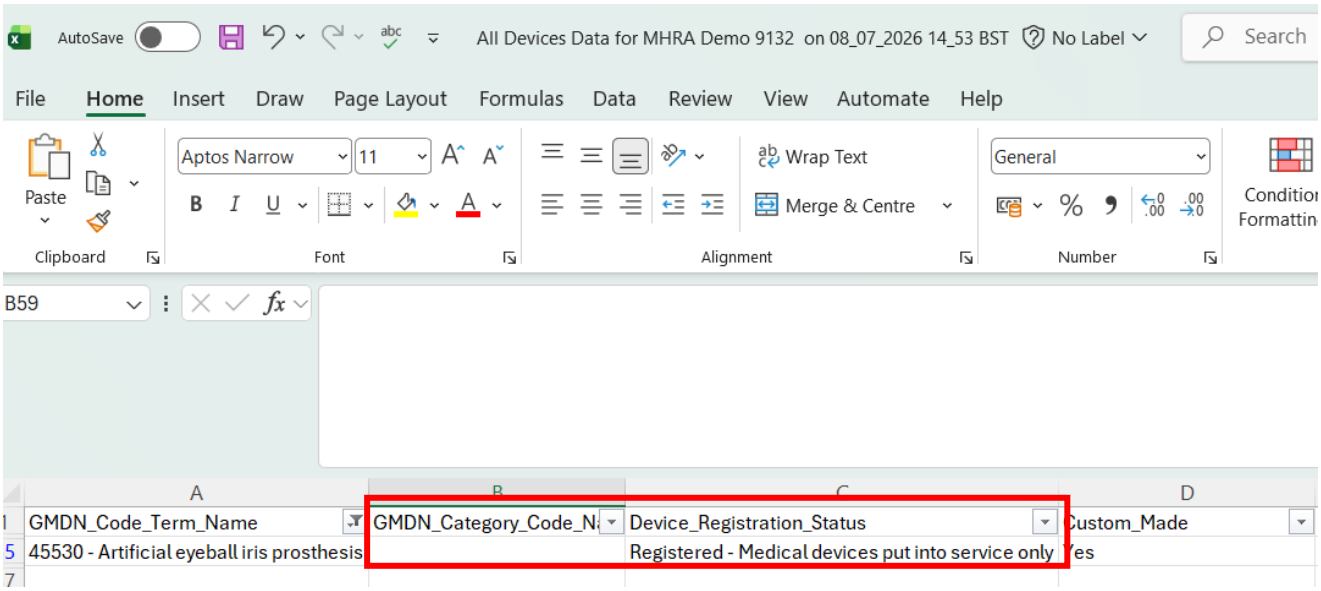
Once you have selected 'Yes', all underlying products will immediately be assigned a status of 'Put into service only'. You cannot change this status. It is not possible to change the status back to 'Placed on the market'.

You cannot order Certificates of Free Sale for medical devices that are put into service only.



Important note: If the same device is both placed on the market and put into service *you must not* tick the 'Put into service only' box. If you wish to register devices that you only put into service, please see below.

Once you have updated each appropriate device individually, please Export all Devices data to Excel to check the new registration status. Instructions can be found in the Device Registration Reference Guide.



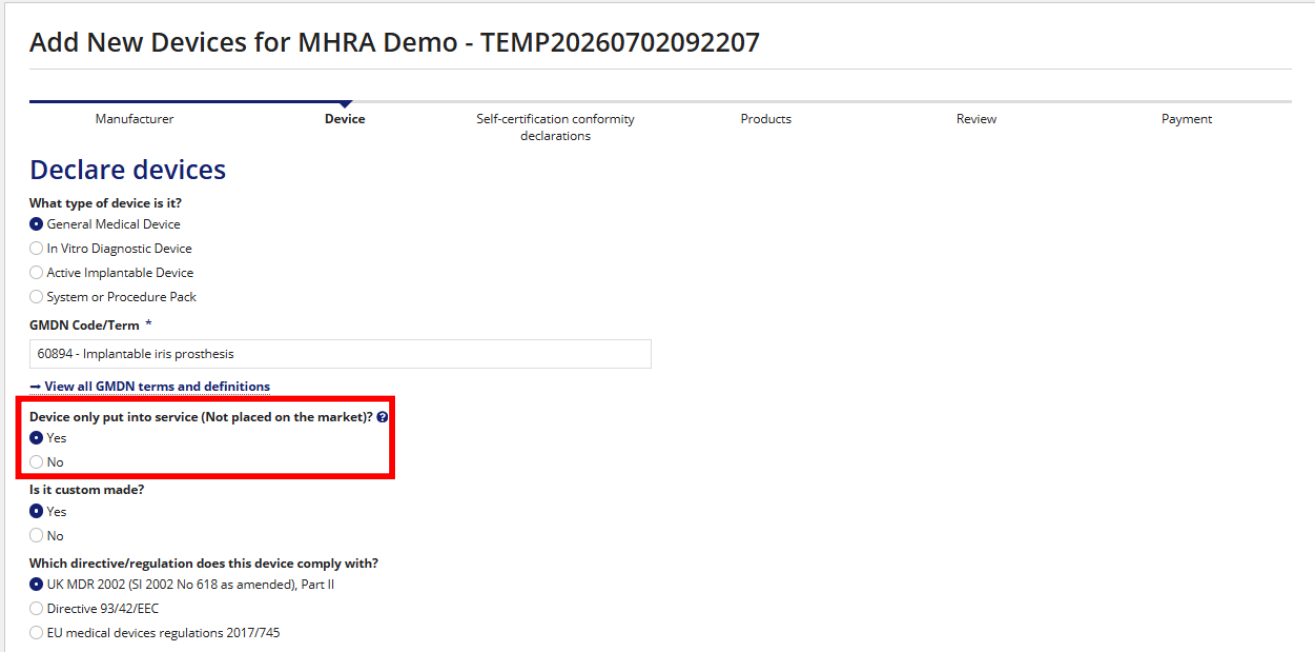
Important note: Devices that are Put into Service only will have a GMDN® Code however the associated GMDN® Category will not appear; therefore, this column will be empty on the Export Devices data to Excel file. GMDN® Categories are only used within DORS for the purposes of fee calculation.

New device registrations

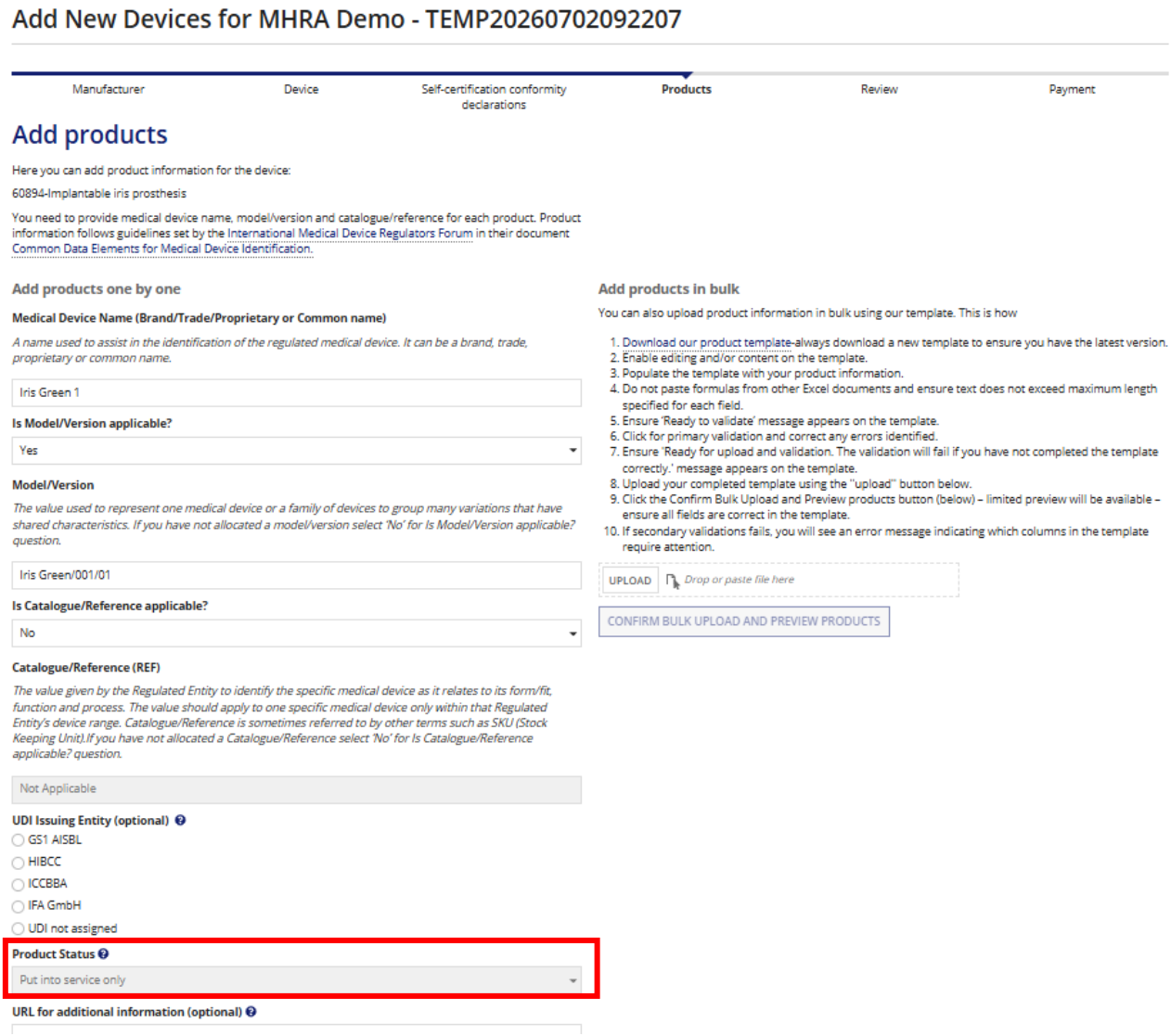
If you wish to register new devices that you only put into service:

Follow the Add Device instructions in the Device Registration Reference Guide.

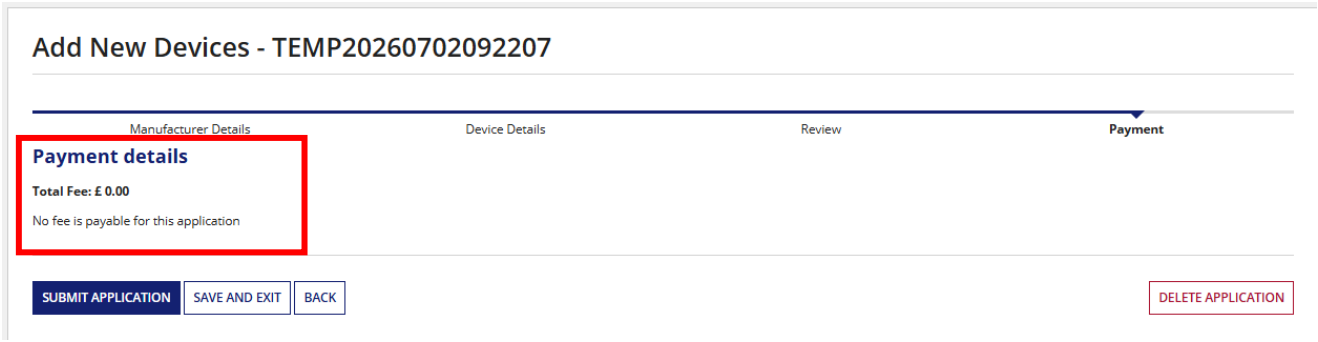
Under the GMDN Code you will see a tick box to enable you to indicate that the device is put into service only:



Once you have selected ‘Yes’, all underlying products will immediately be assigned a status of ‘Put into service only’. You cannot change this status. Once the device is registered you cannot change the status to placed on the market, you will need to unregister the device that is put into service and re-register the device as placed on the market.



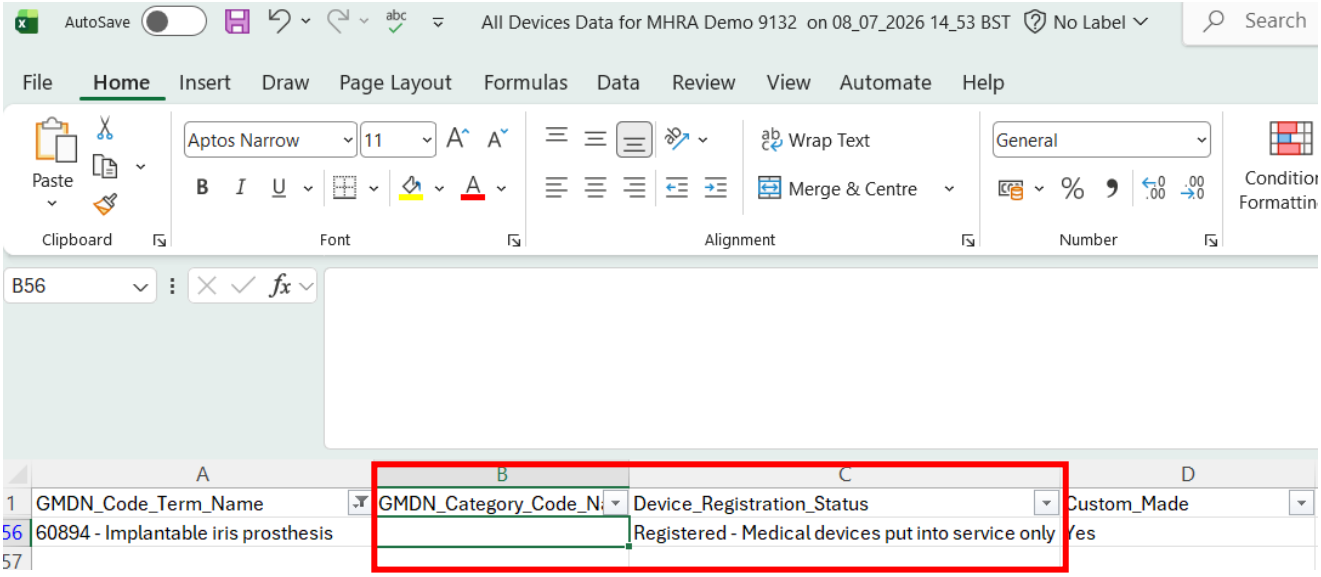
You will not be charged to register devices that are put into service only.



Important notes: If the same device is both placed on the market and put into service, please register the device that you place on the market first and then, optionally, register the device that you only put into service.

You cannot order Certificates of Free Sale for medical devices that are put into service only.

Once you have successfully registered the device/s, please Export all Devices data to Excel to check the registration status. Instructions can be found in the Device Registration Reference Guide.



Important note: Devices that are Put into Service only will have a GMDN® Code however the associated GMDN® Category will not appear; therefore, this column will be empty on the Export Devices data to Excel file. GMDN® Categories are only used within DORS for the purposes of fee calculation.

Keeping your account up to date

Organisations who place devices on the market only

If all your registered devices are placed on the market, no further action is required. You will need to pay the annual fee that was calculated on 1 April 2026, if you have not done so already.

Organisations who place devices on the market and put them into service

Organisations may find that, for the same device type, there are some devices that are placed on the market and others that are put into service only. For example, if these devices are only provided to patients within the same Trust, this would be putting into service. However, the devices may also be provided to a different NHS Trust. Distribution of these devices to another NHS Trust would constitute placing them on the market, and registration with the MHRA is required, and the fee is applicable.

If you place products with the same Global Medical Device Nomenclature (GMDN®) both on the market and put them into service, the fee will remain payable for the device category, for the device that is placed on the market. Guidance on how the new annual fee is calculated can be found here.

If you have a mixture of devices that you place on the market and devices that you put into service only, you should update your registration records to indicate the devices that are put into service only.

Important information: You must do this no later than **11 September 2026**. If you do not take the requested action by this date, MHRA will consider this confirmation that you are placing any devices that remain on the account on the market, in which case the annual fee for 2026/27 will remain payable.

Organisations who put devices into service only

If you only put devices into service, you should update your registration records to indicate that all your devices are put into service only.

Important information: You must do this no later than **11 September 2026**. If you do not take the requested action by this date, MHRA will consider this confirmation that you are placing any devices that remain on the account on the market, in which case the annual fee for 2026/27 will remain payable.

New medical device registrations

Please ensure that you only register devices that fall within the definition of a medical device.

If you place a new device on the market in GB or NI, registration is required and the pro rata fee will be payable to 31 March 2027. Refer to the fees guidance.

If you put a new device into service only, the MHRA encourages you to register the device and use the put into service only function. Refer to registering devices put into service only guidance. No fee will be payable.

Updates to the 2026/27 annual fee

Recalculation of the 2026/27 annual fee

Once records are accurate, the MHRA will recalculate the Annual fee for organisations that have updated their registration data to indicate devices are put into service only. This will be undertaken in **September 2026**. Further information on the revised fee amounts, including any actions that you need to take, will be provided in **September 2026**.

Deadline for paying the 1 April 2026 fee

Devices placed on the market

For the 2026/27 annual fee, we have extended the deadline for payment by one month, to 31 July 2026, to give customers additional time to adjust to the new fee structure and ensure that the correct devices are registered. **Accounts that have not paid the Annual Fee will remain active during this extended period**.

Important note: If all your devices are placed on the market, you must pay the annual fee that was calculated on 1 April 2026, if you have not done so already. The deadline for payment is **31 July 2026.** Please follow the **Annual Fee** instructions in the Account Management Reference Guide. There is also a video tutorial available.

Devices put into service only

If you have already paid the registration fee for the 2026/27 fee period, you will be refunded for any GMDN® Categories where all devices in the Category are put into service only. Further details on the refunds due will be provided in September 2026. No refunds will be given for devices registered before 31 March 2026.

Please update your device registration records using the put into service only function on DORS.

Important note: If you have registered any devices that are put into service only, and you have not yet paid the annual fee, please **do not make payment at this stage**. Accounts that have not paid the Annual Fee, and are eligible to do so, will remain active at this stage.

Devices registered since 1 April 2026 that are put into service only

Please update the device registration details using the put into service only function on DORS. Please follow the instructions in DORS functionality to identify devices put into service.

Refunds will be provided for any devices that are put into service only. Further details on the refund process will be provided in September 2026.

Devices put into service unregistered since 1 April 2026

If you have unregistered devices that you only put into service since 1 April 2026 and provided a reason for unregistering other than ‘Medical Devices put into service only’, please email info@mhra.gov.uk with the **Account Amendment** application number, confirmation that you only put the devices in the application into service, and your contact details.

The MHRA will amend the unregister reason to ‘Medical Devices put into service only’ and recalculate the Annual fee to exclude devices put into service only.

Requirements to pay the Annual fee

The MHRA will be reviewing changes to the registration status of devices on DORS for those indicating that they have put devices into service only. If we have concerns, or are unsure whether you have correctly categorised your devices, we may contact you for further information.

The MHRA will publish further information on how we will manage accounts with unpaid fees in September 2026.

Registration of devices placed on the market plays a vital role in the visibility and traceability and is a requirement of the MDR 2002.

Contact the MHRA

If you have a query that is not answered by the guidance, please email info@mhra.gov.uk with subject heading '*Registration and fees for devices Put into service only*'

We are actively monitoring enquiries relating to the 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.