Placing on the Market vs Putting into Service based on MHRA guidance published 20 July 2026.

Introduction

The MHRA updated its official medical device registration guidance on 20 July 2026 to clarify the distinction between devices placed on the market and those put into service only. During August 2026 the OSA, ABDO and other sector organisations sought further clarification from the MHRA on how this guidance applies to optical practices and glazing arrangements, particularly when determining whether MHRA registration and fees apply. Further clarification was subsequently provided by the MHRA under reference CEC 262710 and CEC 266641 regarding the regulatory status of glazed prescription spectacles.

This guide provides a practical interpretation of that guidance for optical practices that manufacture or glaze prescription spectacles. It explains how the supply route affects MHRA registration and fees and provides step-by-step DORS registration instructions.

Status of finished prescription spectacles.

Ophthalmic lenses and spectacle frames are separate medical devices and must carry the appropriate CE or UKCA marking. When a business combines lenses and a spectacle frame through glazing to achieve the intended medical purpose of vision correction, the completed prescription spectacles are considered a new device under the Medical Devices Regulations 2002. The organisation carrying out the assembly must comply with the applicable regulatory requirements. Whether MHRA registration is mandatory then depends on whether the finished device is placed on the market, put into service only, or supplied through both routes.

The CE or UKCA marking of the component lenses and frame does not, by itself, determine the registration position of the completed spectacles. The supply route of the new finished device must be assessed separately.

Supply route.

Before registering, the optical practice or company assembling the completed spectacles should identify the organisation responsible for the new finished device and assess its complete supply route. This includes who first receives the finished device, whether it is supplied or distributed to another legal entity, and whether it is first made available directly to the intended final user (patient).

The MHRA distinguishes between two regulatory concepts: placing a device on the market and putting a device into service. Depending on the supply arrangement, a device may be placed on the market, put into service only, or the same device type may be supplied through both routes.

Situation	Practical description	MHRA registration	Fee
Placed on the market	Device is first supplied/distributed on the GB market, including supply to another company	Required	Applicable
Put into service only	The device is manufactured and first made available directly to the intended final user without prior marketing or distribution, or sale or transfer of the finished device to another legal entity.	Voluntary and encouraged.	No fee
Both supply routes used	Some devices of the same device type are placed on the market, while others are put into service only.	Required	Applicable

Where a device qualifies as put into service only, MHRA registration is voluntary and encouraged. If you choose to register it, select the 'put into service only' option in DORS; no registration fee applies. Do not select this option for a device that is also placed on the market.

Scope - Great Britain only

This guidance applies to Great Britain (England, Wales and Scotland). Medical devices supplied in Northern Ireland are subject to separate requirements under the Windsor Framework and EU medical device legislation. The GB decision flowchart and DORS instructions in this guide should not be applied automatically to Northern Ireland.

Important note

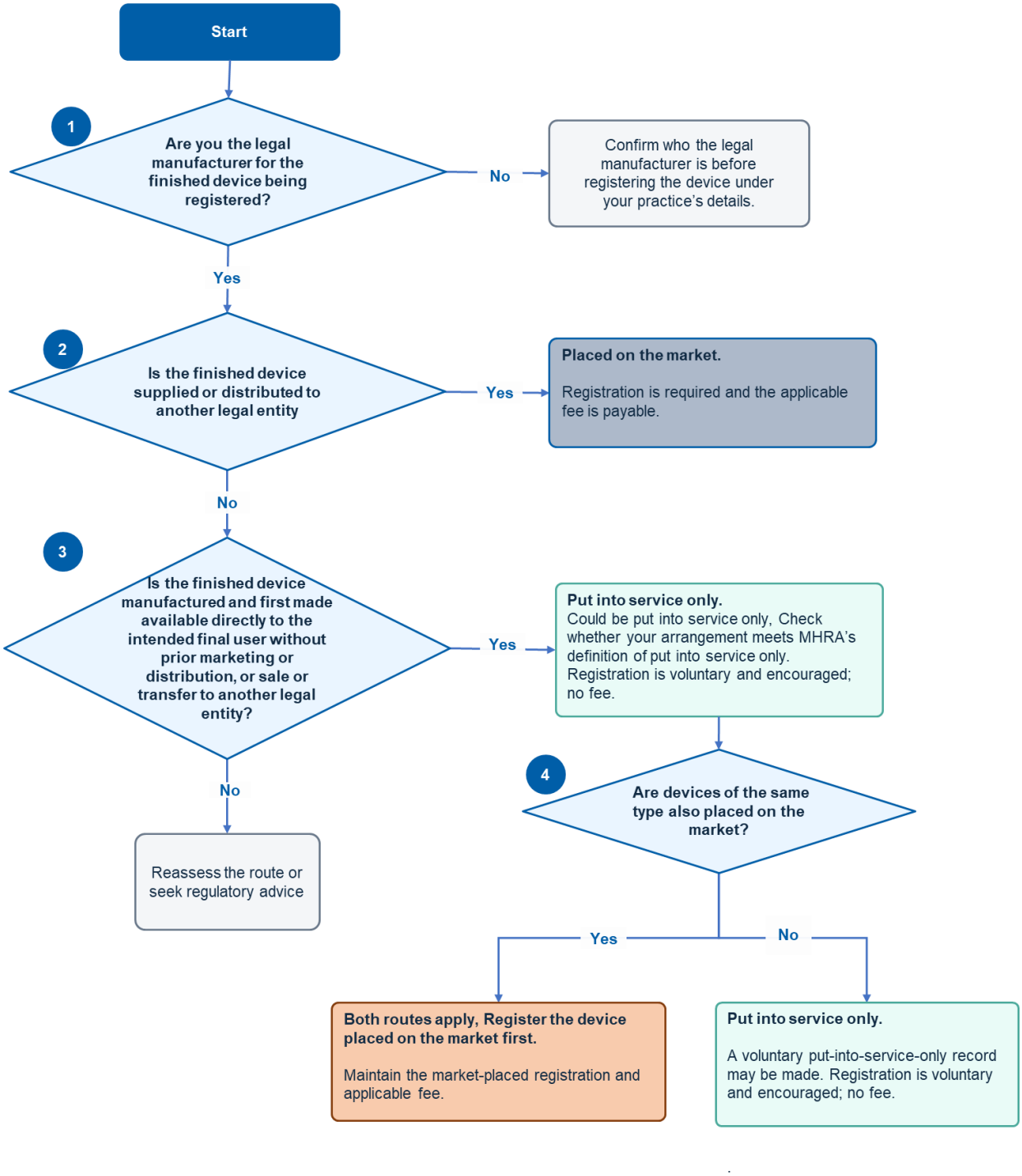
Direct supply to the practice's own patient could be considered put into service only, but this is conditional rather than automatic. The full supply route must be assessed. If the same device is also placed on the market, do not mark that registration as put into service only.

Does your practice need to register with the MHRA?

Assess the complete supply route before using the decision flow below. Direct supply to the final user could be considered put into service only, but only where the device has not also been placed on the market.

Registration decision flow - Great Britain only: Use the actual supply arrangement, considering the legal entity and the complete route from manufacture to the intended final user rather than the physical location of glazing or dispensing.

The decision flow and DORS instructions apply to Great Britain. Northern Ireland remains subject to the Windsor Framework and applicable EU medical-device requirements. The appropriate route depends on device classification and the precise manufacturing and supply arrangement.



Same legal entity

Movement of spectacles or lenses between branches or sites of the same legal entity does not, by itself, constitute placing the device on the market. However, internal movement alone does not establish that a device is put into service only; the complete supply arrangement must still be assessed.

Group practices, central glazing and multi-site operations

For group practices, central glazing facilities and multi-site operations, the key considerations are the company ownership and legal entity , rather than the physical location where the spectacles are glazed or dispensed.

In its clarification to OSA dated 27 August 2026, the MHRA confirmed that devices may be moved between sites or branches of the same legal entity without that movement itself constituting placing on the market. For example, spectacles may be glazed at a central facility and transferred to another branch of the same company for final dispensing to the patient and be classed as “putting into service”.

However this does not automatically establish that the device is put into service only. The organisation must still assess the complete supply route, including whether the finished device is marketed, distributed or transferred to another legal entity before it reaches the final user.

Where completed spectacles are transferred or distributed to a separate legal entity, this constitutes placing on the market and the applicable MHRA registration requirements apply. Where registration is required, the legal entity acting as the manufacturer must hold the appropriate registration for the devices for which it is responsible.

Where the same legal entity both places some devices on the market and puts others of the same device type into service only, the market-placed device must remain registered, and the relevant category fee remains applicable.

Promotional and second pair offers

Where both pairs are glazed to the individual patient's prescription and supplied directly to that patient, the MHRA Device Registrations team clarified on 23 October 2026 that a promotional offer does not, by itself, alter the put-into-service position. The complete manufacturing and supply route must still satisfy the criteria for putting into service only.

Legal manufacturer and regulatory responsibility.

The physical location of glazing is not, by itself, decisive. The business should establish which legal entity is the legal manufacturer or otherwise responsible for the finished prescription spectacles, and then assess the complete route by which the finished device reaches the intended final user.

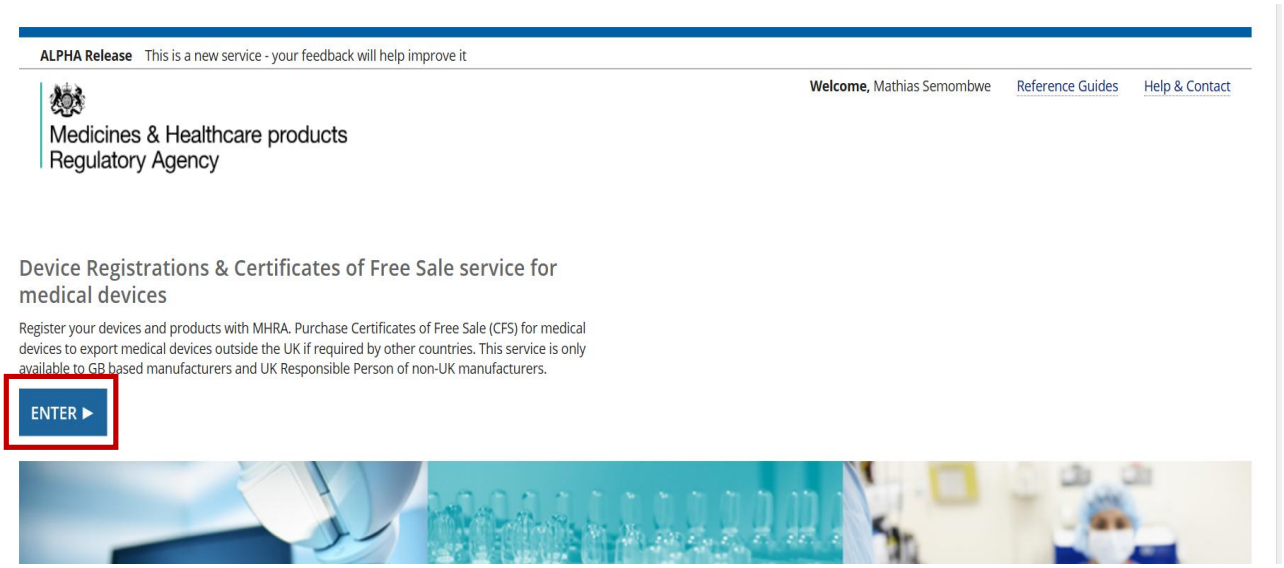
Step-by-step: registering on MHRA DORS

Step 1 - Create or access your MHRA DORS account.

Go to the MHRA Device Online Registration System and create an organisation account if you do not already have one. Once access is available, log in and select ENTER under "Device Registrations & Certificates of Free Sale service for medical devices"

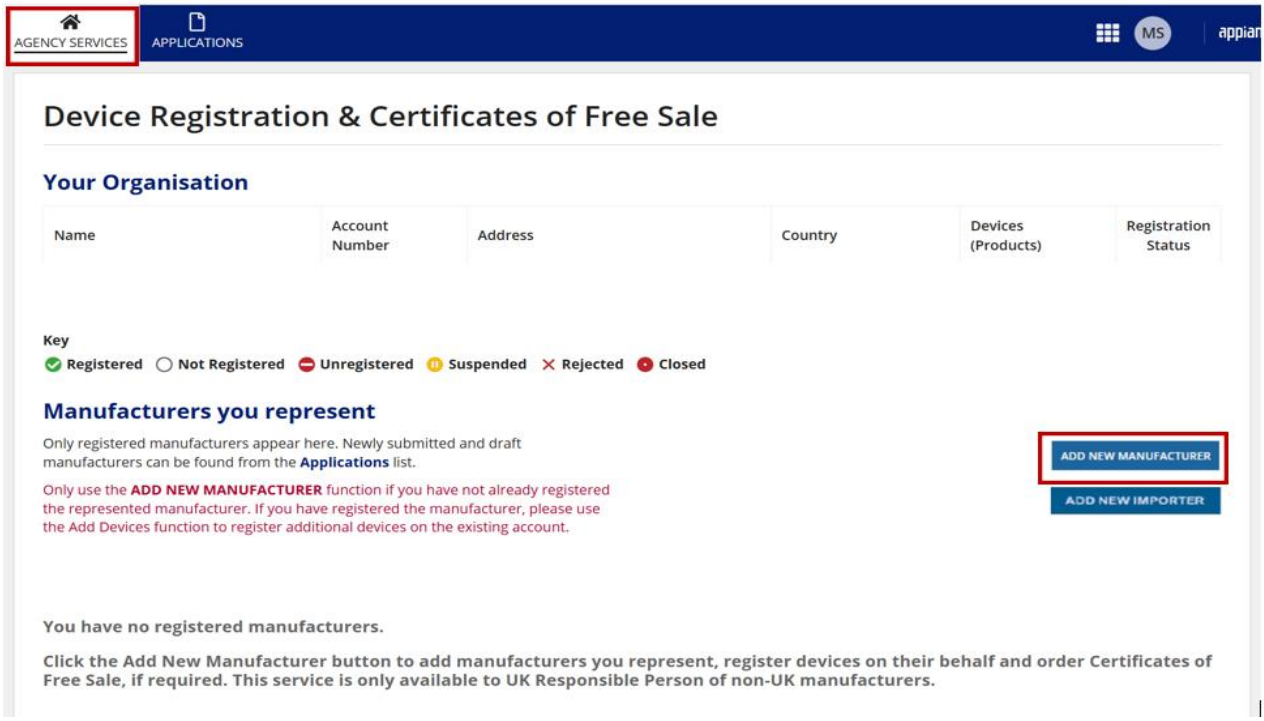
Before starting DORS

First establish whether the device is placed on the market, put into service only, or supplied through both routes. The DORS process should only be completed once the correct registration route has been determined.



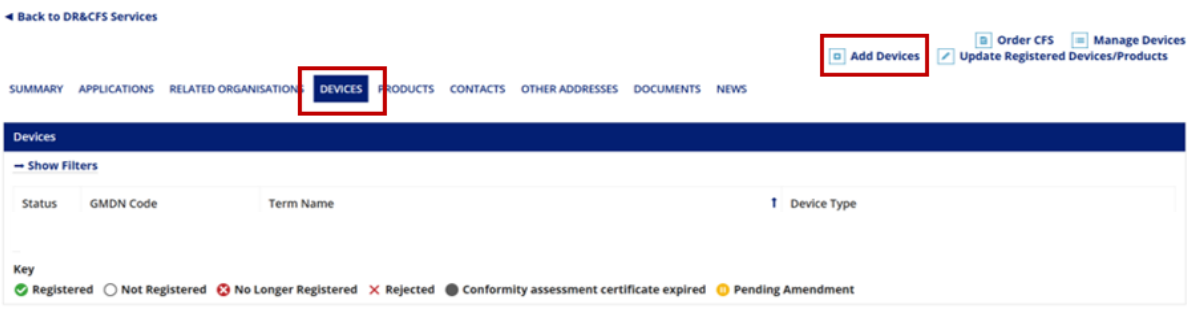
Step 2 - Select the legal manufacturer

On the Agency Services tab, select your organisation that is the legal manufacturer of the device. Check that its details are correct before adding devices. The devices must always be registered against the organisation that is the legal manufacturer.



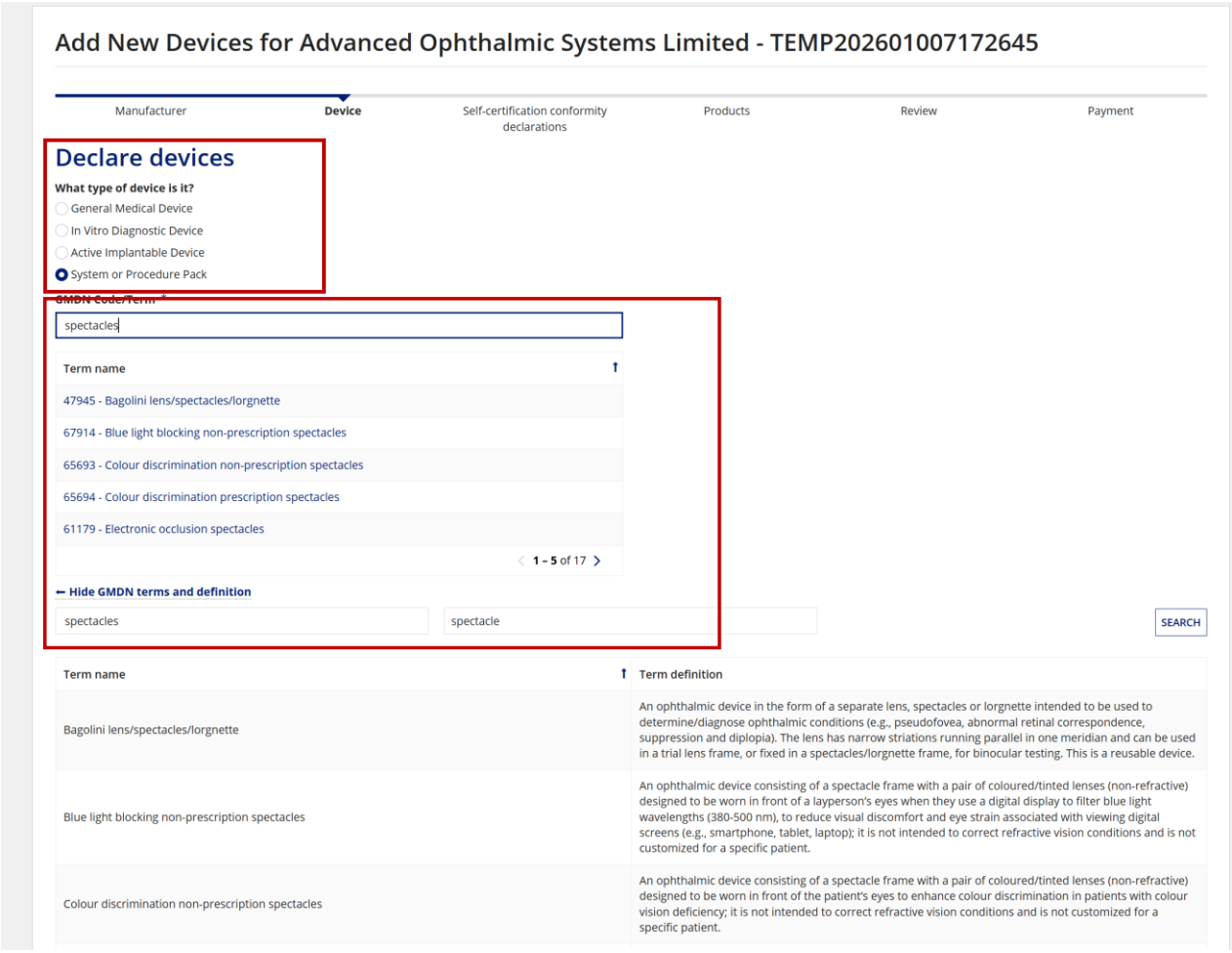
Step 3 - Select “Devices” and “Add Devices”

Open the Devices tab, review any existing registrations, and select Add Devices to begin a new registration application



Step 4 - Select the device type and GMDN

Select the appropriate device type and search for the correct Global Medical Device Nomenclature (GMDN) term. Use the term that accurately describes the device being registered. Do not select a term simply because it produces a preferred fee outcome.



Step 5 - Confirm whether the device is put into service

Under the GMDN information, DORS asks whether the device is “only put into service (Not placed on the market)”. This is the key decision point where the practice must select Yes or No depending on its actual supply arrangement.

Select Yes where the device is classified as put into service only after assessing the complete supply route. Direct patient supply alone is not sufficient if the device has also been placed on the market.

Select No where the device is placed on the market, including where the finished device is supplied or distributed to another legal entity

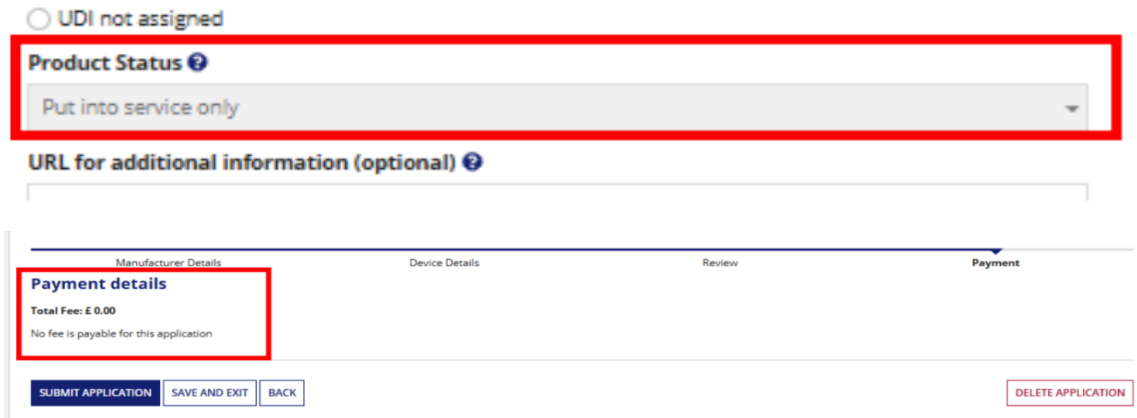


Step 6 - Complete device and product information

Continue through the DORS workflow and complete the fields relevant to the device, including the applicable regulatory route, conformity documentation and product information. The exact fields vary according to device type and regulatory status.

- Check the legal manufacturer details.
- Use the correct GMDN term and device type.
- Select the applicable legislation/directive accurately.
- Upload or link the required conformity documentation.
- Enter the product name and other required product details.

Review all information before submitting the application. For a device correctly registered as put into service only, the product status should show “Put into service only”.



Step 7 - Submit and confirm registration

Review the registration information carefully, submit the application and complete any payment required for the applicable registration route. No registration fee applies to a device correctly recorded as put into service only.

Important note

Once a new registration is completed as put into service only, the status cannot be changed directly to placed on the market. If the supply route later changes, the device must be unregistered and re-registered as placed on the market. If the same device is both placed on the market and put into service, do not mark that registration as put into service only.

The MHRA has published official device registration guidance providing detailed, step-by-step instructions on how to complete registration in DORS. Members are strongly encouraged to refer to and follow the MHRA guidance when completing or updating their device registrations.

Official MHRA guidance

- Register medical devices to place on the market - GOV.UK
- MHRA Device Registration Reference Guide – April 2026
- MHRA guidance on placing on the market and putting into service

Key Considerations for members

- **Registration is not product approval:** Registering a device with the MHRA means that the manufacturer and device details have been recorded in the MHRA registration system. It does not mean that the MHRA has assessed, approved or endorsed the device, or confirmed that it complies with all applicable regulatory requirements.

- **Manufacturer responsibility:** Manufacturers remain responsible for ensuring that their devices meet the applicable regulatory requirements, post-market surveillance (PMS) obligations and have completed the appropriate conformity assessment before they are placed on the market or put into service

- **No registration fee does not remove regulatory obligations:** A zero MHRA registration fee only means that no registration fee is charged for devices recorded as put into service only. It does not exempt the device or manufacturer from the applicable medical device regulatory requirements, including post-market surveillance and vigilance obligations.

- **Use the correct registration route:** The “put into service only” option should only be selected where it accurately reflects how the device is manufactured and supplied to the final user. It should not be selected simply to avoid MHRA registration fees.

- **If your practice uses both supply routes:** If the same device type is placed on the market and also put into service only, follow MHRA’s instructions for maintaining the market-placed registration and, where desired, a separate put-into-service-only registration.

- **Certificates of Free Sale:** Certificates of Free Sale cannot be ordered from the MHRA for devices registered as put into service only.

- **Group practices / central glazing:** Movement of spectacles or lenses between sites of the same legal entity does not, by itself, constitute placing the device on the market. It also does not automatically establish put-into-service-only status. Where devices are supplied or transferred to a separate legal entity, this constitutes placing on the market and the applicable MHRA registration requirements apply.

- **Great Britain only.**
  This guide applies to Great Britain (England, Wales and Scotland) only. Northern Ireland is subject to separate requirements under the Windsor Framework and applicable EU medical device legislation.

  From 28 May 2026, non-custom-made devices for the Northern Ireland market are subject to the applicable EUDAMED registration requirements, while custom-made devices continue to be registered with the MHRA.

  For custom-made devices, MHRA registration is voluntary and fee-free where the device qualifies as put into service only. Where a custom-made device is placed on the Northern Ireland market, it must be registered with the MHRA within 28 days. Applicable EU medical device requirements, including post-market surveillance obligations, continue to apply.

- **Prescription spectacles in Northern Ireland**
  The appropriate registration route depends on whether the finished spectacles are custom-made or non-custom-made and on how they are manufactured and supplied. This guide does not determine the classification of every prescription spectacle arrangement. Practices operating in Northern Ireland should establish the applicable device classification and assess the complete manufacturing and supply route before deciding whether registration is required through the MHRA or EUDAMED. Where the position remains uncertain, the practice should seek advice from the MHRA or an appropriately qualified regulatory or legal adviser.

Member checklist before selecting “Yes”

1. I have confirmed which organisation combines the lenses and frame and is responsible for the completed prescription spectacles as a new device and system.
2. I have confirmed who the legal manufacturer is.
3. I have assessed the complete supply route and identified who first receives the finished device.
4. I have confirmed that the device is not supplied/distributed to another company before reaching the final user.
5. I have documented why the device could properly be classified as put into service only.
6. I understand that the status cannot simply be changed later to placed on the market.
7. I understand that regulatory and PMS obligations continue even where no DORS registration fee applies.
8. I have checked whether devices of the same device type are also placed on the market.

9. Where Northern Ireland is relevant, I have established whether the device is custom-made or non-custom-made and identified the appropriate MHRA or EUDAMED registration route.

References:

1. MHRA, Register medical devices to place on the market, GOV.UK, updated 20 July 2026.
2. MHRA, Registration requirements for medical devices placed on the market and put into service, July 2026.
3. MHRA, Device Registration Reference Guide, Version April 2026 v1.
4. MHRA, Legal requirements for specific medical devices - ophthalmic products, updated 20 July 2026.
5. MHRA, Regulation of medical devices in Northern Ireland, GOV.UK.
6. MHRA Customer Services, CEC 262710, correspondence to OSA dated 27 August 2026
7. MHRA Customer Experience Centre, CEC 266641, clarification on glazing, finished prescription spectacles and putting into service only dated 14/10/26

Disclaimer

This guidance is intended to support the optical industry in understanding the MHRA registration process. Whether a particular device is placed on the market or put into service depends on the precise manufacturing, marketing, distribution and supply arrangements. This guide is a practical interpretation of published MHRA guidance. It does not constitute legal advice or a definitive statement of the law. Where the correct regulatory route is uncertain, members should consult the MHRA or obtain appropriate regulatory or legal advice.