Glazed prescription spectacles: do you need to register with the MHRA?

Applies in England, Scotland and Wales. Summaries MHRA guidance updated 20 July 2026 and MHRA clarifications CEC 262710 (27 Aug 2026) and CEC 266641 (14 Oct 2026). Read alongside the full guidance.

In brief.

Once lenses are fitted into a frame, the finished spectacles become a new medical device. The manufacturer must comply with applicable regulatory requirements. Whether you must register in device online registration system (DORS), however, depends on one thing: where the completed spectacles go next.

- They leave your legal entity (sold or passed to another company) → placed on the market: registration is mandatory, and a fee is payable.
- They stay within your legal entity and go straight to the patient, and none of that device type is supplied elsewhere → put into service only: registration is optional and free.

Find your supply arrangement.

Your arrangement	Regulatory route	DORS registration	Fee
Single practice: glazed in-house and dispensed to that practice's own patient	Put into service only	Optional	Free
Multi-branch business: glazed at a central lab or another branch, then dispensed by the same company	put into service only	Optional	Free
Lab or practice sending completed spectacles to a different company, e.g. an independent, a franchise or a subsidiary with its own legal identity	Placed on the market	Mandatory	Payable
Mixed: the same device type goes to your own patients and to other companies	Both routes	Mandatory for the market-placed devices	Payable

Transferring finished spectacles between branches of the same company does not, by itself, constitute placing them on the market. Whether MHRA registration is required depends on how the finished spectacles are ultimately supplied.

Four-point check before you decide.

1. **Name the manufacturer**: Confirm which legal entity is responsible for assembling the finished spectacles?
2. **Trace the pair.** Follow it from the glazing bench to the patient. Does ownership pass to any other company?
3. **Look across your whole business**. Is any of the same device type sold or supplied to other businesses?
4. **Record your reasoning**. Keep the rationale for your chosen route in your quality records.

Beyond registration.

- A DORS entry is a record, not an approval. The MHRA has not reviewed or endorsed your device.
- Your duties as manufacturer continue whatever the fee. Conformity, safety, vigilance and post-market surveillance all still apply.
- Northern Ireland follows separate rules under the Windsor Framework and EU MDR. Non-custom-made devices have registered in EUDAMED since 28 May 2026, while custom-made devices remain with the MHRA. Take NI-specific advice.

Full guidance and official sources.

For step-by-step DORS instructions, complex group structures, or before amending an existing registration, consult the:

- **Full OSA and ABDO optical industry guidance**.
- MHRA registration guidance.
- MHRA placing / putting into service guidance .
- Northern Ireland guidance.

Based on published MHRA guidance (20 July 2026) and OSA and ABDO correspondence (August–October 2026). Practical interpretation only; not legal advice. Where the applicable route is unclear, contact the MHRA or obtain specialist advice.