



Guidance on Completing an RG2 Form for Medicines and Healthcare Products Regulatory Agency (MHRA) Registration

**This guidance has been developed for the optical sector in collaboration with the
MHRA**

Optical Products as Medical Devices

The **Medical Devices Regulations (2002)**¹, amended in 2008, require all medical devices to carry the CE marking.

In order for devices to carry the CE mark, and thereby be permitted to be retailed in the EU, manufacturers of these devices must be registered with the Medicines and Healthcare products Regulatory Agency (MHRA). Finished prescription spectacles do not need to be CE marked in their own right, providing the constituent frames and lens packaging are properly marked.

Most ophthalmic devices (for example spectacle lenses and frames) are classified as Class I medical devices. This means that manufacturers, own branders and assemblers of these (as defined below) must register with MHRA by completing an RG2 form.²

Contact lenses and solutions, however, are classified differently (as Class IIa and Class IIb products respectively) and are not covered by the RG2 form system.

Custom Made Products

Custom made medical devices are defined as those intended for the sole use of a particular patient, such as artificial eyes or contact lenses made from an eye impression. Prescription spectacles and all other contact lenses do not fall under the definition of custom made devices. Custom made devices do not require a CE marking.

Glazing and Surfacing

Under the Medical Devices Regulations glazing of spectacle frames is classed as assembly and the surfacing of spectacle lenses is classed as manufacturing. If your practice receives remotely edged lenses and fits them into a frame, this is also considered to be assembly. This means that businesses undertaking these tasks, including practices which assemble or glaze spectacles, must be registered with the MHRA using form RG2 (see below).

¹ These regulations are made under **The Medical Devices Regulations (2002)** Act which in turn gives effect in UK law to EU Directive, the Medical Devices Directive 93/42/EEC

² <http://www.mhra.gov.uk/home/groups/es-era/documents/publication/con007514.pdf>

Similarly the supplier of an own brand medical device (eg spectacle frames) must also be registered with MHRA using form RG2.

Registration with the MHRA – Updated Advice

Members are advised to review their current status to ensure they are registered appropriately. If your registration is correct, members only need to submit an updated RG2 form if there is a change in your registration details eg different devices, or company name/address.

All members should also note their duty to contact the MHRA and the manufacturer if there is a serious adverse incident involving a medical device (see below for details).

Optical practices and businesses must be registered as an **assembler of systems and procedure packs** with MHRA if they assemble Class 1 **medical devices** - (see Appendix B for a list of class 1 devices).

Optical practices and businesses must be registered as a **manufacturer** with MHRA if they:

- carry out lens surfacing as part of glazing spectacles
- **manufacture** Class 1 or custom made **medical devices** and **place them on the market** under their own name/trading name
- are an **own brander** (labelling one or more device manufactured by another party as your own)
- place devices showing the CE mark under their own name on the market
- are the **authorised representative** of a manufacturer who does not have a registered place of business in the EU community or if they import these products and place them on the market (this would also apply for example to intermediate suppliers or a buying group that does not operate an optical practice).

Please refer to Annex A for definitions of the items in bold. If none of these categories applies to your practice, you do not need to register with MHRA.

Completing the Updated RG2 form

The **Medical Device Regulations Form RG2** was updated in 2010 to take into account the 2008 amendments to the Medical Device Regulations. Members should complete the RG2 form before they introduce a service or product which requires registration to the market.

Independents or multiple groups

Independent practices should register in their own right (by completing an RG2 form).

For multiple groups the law is not absolutely clear and MHRA will judge each case on its own merits. However to date, where there is a direct managerial link between head office and practices, ie they are one organisation, the MHRA has allowed the head office to register on behalf of their practices. This minimises the administrative burden on all sides as well as making sure that all sites which should be registered are registered.

Multiple groups should continue to operate on this understanding and contact their representative body at the Optical Confederation if they have any problems.

Glazing or Assembly of Spectacles

For **glazing or assembly**, an independent practice should register with the MHRA in its own right (by completing an RG2 form).

However, if a practice is part of a multiple group (including joint ventures or franchises) with a direct managerial link to headquarters), it should be included in the group registration as above.

A **glazier or assembler** must provide the address of their registered place of business and select 'Assembler of System and Procedure Packs' under Part 1, and then complete Part 4 Section 9 with the code 'L5' and Section 9a with 'prescribed spectacles'.

Declaration of Conformity

Please note that practices glazing and assembling spectacles must also complete a Declaration of Conformity, in accordance with the Medical Devices Regulations 2002 14 (1) b. This is in effect a statement that you conform to the manufacturers' instructions and have established internal ordering and processing systems. Please refer to Annex C for a specimen declaration. This should be completed and stored in the practice (or head office as appropriate) for reference.

Own Brand Products and Surfacing

As above, if you supply **own brand products** or if you **carry out surfacing work** in your practice, **you are classified as a manufacturer by the MHRA**. Both independent practices and multiple groups (including joint ventures or franchises), should be registered with the MHRA for this (by completing from RG2) as above.

If supplying own brand products or surfacing, practices and businesses must provide the address of their registered place of business and select 'Manufacturer' under Part 1. These practices and businesses must also complete Part 2 Section 4, and Part 4 Section 7 and 7a.

For registration purposes each ophthalmic medical device is assigned a generic code ie insert code F7 under Section 7 and 'spectacle frames' under 7a. A full list of the relevant ophthalmic generic codes is provided in Annex B.

Practices and businesses should note that they do not need to register individual products, the generic code is sufficient to cover the broad category of product e.g. 'spectacle lenses'. Please check the list in Annex B carefully to ensure that you registered appropriately.

Further information and support

Members should check the generic code on the MHRA website before submitting form RG2 to confirm that the generic codes are still correct at time of completion.

The advice above should cover the majority of circumstances. Additional guidance on completion is provided at the back of the RG2 form and on the MHRA website

www.mhra.gov.uk/Howweregulate/Devices/Registrationofmedicaldevices/RegistrationofmedicaldevicesFrequentlyaskedquestions/index.htm

In cases of difficulty, please contact your Optical Confederation representative body.

For UK registration, members should send the completed RG2 form and Declaration of Conformity to **Registration Scheme Officer, Medicines & Healthcare Products Regulatory Agency, 5 Magenta, 151 Buckingham Palace Road, Victoria, London, SW1W 9SZ**. We would recommend keeping a copy of submitted documents in your practice or head office as these might later be requested, for example by a PCT (see below for information).

The RG2 form is available from the MHRA via the following link [Registration form RG2](#) and is also available on your Optical Confederation representative body's website. The current cost to register with MHRA is £70. NB The registration fee is per form, not per product. Part 3 of the RG2 form provides details for payment. If paying via debit or credit card, a copy of the payment verification should be submitted with the RG2 form.

If businesses operate in another EU member state you will need to contact the local competent authority.

The competent authority for the Republic of Ireland is the Irish Medicines Board (IMB) www.imb.ie.

A full list of competent authorities in the EU is available here:

http://ec.europa.eu/consumers/sectors/medical-devices/files/list-of-contact-points-within-the-national_en.pdf

Once Registered

Practices and businesses will receive a registration number which must be used in all correspondence with the MHRA and must keep the MHRA informed of any change in details, including company name, business address, or discontinuation of product categories. Should you begin to supply additional 'own brand' products, you should also notify MHRA with an updated RG2 form.

A new RG2 form should be submitted (with a £70 fee) for a change of company name, address, additional devices and/or change of authorised representative.

Please note for basic changes such as telephone numbers, contact person, or removal of devices, an RG2 form is not required and therefore no fee will be charged. For changes of this nature please notify the MHRA in writing either via email, ERA@mhra.gsi.gov.uk, or post. Please remember to quote your registration number in all correspondence with MHRA.

Glazing Frames without a CE Marking

Practices should note that the Medical Devices Directive does not cover spectacle frames already owned by a patient. Therefore new lenses can be put into a patient's existing frames (even if they do not have a CE marking).

Primary Care Trusts

Some practices have been in touch about PCTs requiring registration or further information. Whilst it is legitimate for a PCT to check whether a practice is registered, it should be noted that it is the MHRA and not the PCT which oversees registration and regulation of medical devices.

Practices only need to be registered with the MHRA if they manufacture, assemble spectacles or do surfacing work, as above. Optical practices that do not supply these services or products do not need to register with MHRA. Members should get in touch with their LOC or national representative body if requests are made by PCTs that go beyond these requirements.

Adverse Incident Reporting

All serious incidents involving medical devices should be reported to the MHRA Adverse Incident Centre and the manufacturer should also be informed, including the original producer of an 'own brand' product. An adverse incident is an incident that has caused harm or serious harm/death to an individual. This would include, for example, a serious adverse response to a contact lens solution. Contact details to report adverse incidents are available below.

Email: aic@mhra.gsi.gov.uk Tel 020 3080 7080

<http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON111565>

Optical Confederation

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Annex A

Definitions³

Assembler of System and procedure packs

Person responsible for putting together a system or procedure pack containing both CE marked and non-CE marked products, in accordance with Article 12 of the Medical Devices Directive. (Assembly or glazing of spectacles comes under this category.)

Authorised Representatives

A person designated by the manufacturer with an established place of business within the European Community (EC) acting on behalf of a manufacturer based outside the EC.

Manufacturer

The person who places the product on the market under his own name. The person is responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name regardless of whether these operations are carried out by that person himself or on his behalf by a third party; or any other person who assembles, packages, processes, fully refurbishes or labels one or more ready made products to place on the market under his own name.

Medical Device

Any instrument, apparatus, appliance, material or other article which is intended by the manufacturer to be used for human beings for the purpose of diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.

Own Brander

The person who places the product on the market under his own name or trademark and is therefore the manufacturer (as defined) for the purpose of the regulations. The own brander may not have designed, labelled or packaged the product but the regulatory responsibility rests with the own brander. The own brander must ensure that the conformity assessment procedure is followed, the RG2 form is completed and lodged, the CE marking is applied and that post market vigilance obligations are satisfied.

Placing on the market

The first supply of a medical device by the manufacturer (as defined by MHRA – see above) in return for payment, or free of charge, of a new or fully refurbished device.

³ Based on MHRA guidance and supporting legislation

Annex B

Ophthalmic Class 1 Classification of Medical Devices

List Derived from Article 14 of the MDD 93/42EC

F 1 Lamps (Ophthalmic Examination)

F 2 Fundus Cameras/Keratometers/Slit Lamp Microscopes and Associated Software

F 3 Low Vision Aids

F 4 Operating Room Microscopes/Magnification Systems

F 5 Ophthalmoscopes/ Retinoscopes

F 6 Spectacle Lenses

F 7 Spectacle Frames

F 8 Ready-Made Spectacles (Non-Prescribed)

F 9 Sight Testing Devices

O 9 Schirmer Tear Test (Sterile Product) (Ophthalmic and Optical Devices)

Z 45 Class I Tonometer(Reusable)

Z 105 Eye Speculums(Ophthalmic and Optical Devices)

Z130 Contact Lens accessories(Ophthalmic and Optical Devices)

Z 148 Eye Baths/Irrigation Systems And Eyewash Solutions(Ophthalmic and Optical Devices)

System and Procedure Packs (Article 12)

L 5 Prescribed Spectacles

ANNEX C

SPECIMEN
DECLARATION OF CONFORMITY
by

Assemblers of Individually Prescribed Corrective Spectacles
Assembled from Class I CE marked medical devices
as required by Regulation 14(1) of the Medical Devices Regulations 2002

a) Mutual Compatibility

All CE marked frames and lenses are designed and manufactured to be mutually compatible as a result of the process of assembly (glazing). The essential mutual compatibility of frames and lenses has been established over many years and can be judged by a qualified optician or a suitably trained technician. As part of the process of assembly, we adapt each CE marked lens or pair of lenses, so that they fit, and are compatible with, the CE marked frame.

We maintain a file of manufacturers' instructions. Whenever manufacturers of frames and/or lenses issue instructions, which are at variance with our normal process of assembly, we follow those instructions.

b) Packaging and Relevant Information

Our professional practice and assembly facility are co-located. All parts and/or assembled spectacles are placed in trays or bags to ensure that they remain undamaged during all processes and until collection by the practice from the assembly facility.

Additional information is included where appropriate, i.e. when supplying new or high technology lens or treatment. This normally takes the form of a user instruction from the manufacturer. Professional staff give clinical advice and any cleaning and care advice that is necessary.

Warranty and any other information may be included as appropriate.

c) Internal Control

Internal control forms part of our ordering and processing system. It is documented and consists of:

- a review of the prescription and the order for assembly
- the selection of the lenses (where we have a choice)
- the process of assembly
- continual inspection of the process of the assembly

d) Declaration

I, the undersigned, declare that we work in accordance with the process described above.

Signed:..... Date

Name of organisation.....ⁱ

ⁱThis is a sample Declaration of Conformity which can be accessed via the following link
http://www.aop.org.uk/uploads/uploaded_files/medical_devices_declaration_of_conformity_for_assemblers.pdf

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