# Medical Devices Regulation (MDR)

*Guideline to ECOO members on what obligations are to be fulfilled by opticians/optometrists under the Medical Devices Regulation (MDR)*

**MAY 2021**

**REGULATION (EU) 2017/745**
**(Medical Devices Regulation – MDR)**

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

## INTRODUCTION

The Medical Devices Regulation (MDR) was published in the EU Official Journal on 5 May 2017 and became effective as of 25 May 2017. The original implementation period of three years has been extended by one year, which means that the "Date of Application" is 26 May 2021. As a regulation, the MDR is immediately enforceable as law in all Member States simultaneously as of that date. In addition, the MDR includes requirements that Member States should implement via national laws. The MDR replaces the existing Medical Devices Directive (93/42/EEC) (MDD) and the Active Implantable Medical Devices Directive (90/385/EEC) (AIMDD).

## BACKGROUND

The EU embarked on a full regulatory overhaul of its legislation governing medical devices following the Poly Implant Prothese (PIP) Breast Implant scandal. The goal of this complete review was to provide high levels of safety in the oversight of medical devices and restoring public confidence.

*In summary, **the MDR is legislation to protect consumers** and the key elements are:*

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available. This will help to ensure that medical devices are safe;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market. This will allow manufacturers to act swiftly when concerns arise and help them to improve their devices continuously on the basis of actual data;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number. This will allow fast and effective measures in case of safety problems;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU. This will enable them to make better informed decisions.

# CLASSES OF MEDICAL DEVICES

The MDR classifies medical devices into four risk categories
Class I (lowest risk), Class IIa, Class IIb and Class III (highest risk).

*The classifications reflect the risk profile of a device.*

- For Class I the manufacturer needs to provide a certificate of conformity, which an eye care practitioner then needs to provide to the end consumer/patient.
- Classes IIa, IIb and III need to be reviewed by a notified body. Classification requires a technical file, a quality management system for production (e.g. ISO 9000 series - note: ISO certification is not mandatory, it can however be a system established on its own by the entrepreneur) and a vigilance system (post market-surveillance)

The below table is a schematic overview of conformity assessment procedures depending on the class of device. Please refer to MDR Article 52 and the relevant Annexes for full provisions:

| **Conformity assessment procedure** / **Class** | Annex IX: quality management system and technical documentation | | Annex X: type examination | | Annex XI: product conformity verification | | Annex IV: declaration of conformity |
|---|---|---|---|---|---|---|---|
| Class I | | | | | | | ● |
| Class I sterile, measuring, reusable surgical instruments | I,III | | | or | A | and | ● |
| Class IIa | I,II(4),III | | | or | 10 or 18 | and | ● |
| Class IIb | I,II(4),III | or | ● | and | A or B | and | ● |
| Class III<br>Class IIb implantable (except sutures etc.) | ● | or | ● | and | A or B | and | ● |

● - annex applies in full ◐ - annex applies in part, sections listed under symbol

*(Source: MDCG Guidance on classification of medical devices)*

# RELEVANCE OF THE MDR TO OPTICIANS AND OPTOMETRISTS IN EUROPE

The MDR applies to all actors on the market that work with, prescribe, supply/distribute or manufacture medical devices.

There are over 500.000 types of medical devices and In Vitro Diagnostic medical devices (IVDs) on the EU market, of which optical/optometric related products are only a fraction. The MDR has been designed to cover all medical devices and therefore does not fit every scenario and use of by a specific professional group easily. This leaves room for interpretation and questions, which the European Commission and Member States aim to address via guidance documents. These guidance documents often reflect a compromise agreement in an effort to harmonise practices across Europe.

Contact lenses (both corrective and plano – Class IIa), solutions (Class IIb), corrective spectacle frames (Class I) and ophthalmic lenses (Class I) are all medical devices and all fall within the scope of the MDR. Discussions have been ongoing for many months as to what MDR requirements apply to corrective spectacles (Class I), because they have been classified differently in each Member State under the MDD but there are no clear provisions under the MDR for a device that is composed of two separate medical devices. This question has been clarified in a Q&A document adopted by Member States in March 2021 (see below).

# MDR: A PRODUCT LEGISLATION

The MDR is a product legislation, this means that it regulates the requirements related to a product and does not address how a professional group is recognised and regulated at national level, including their scope of practice. This remains a national competence.

The question as to who has to fulfil which requirements does not depend on the job title of a person but what specific tasks they perform in supplying the population with medical devices that are regulated by the MDR.

- Those who supply medical devices to customers/patients as the last link in the supply chain will typically fulfill the **distributor** obligations under the MDR. If the distributor however chooses to import medical devices or CE-marked components from countries outside the EU, they will have to fulfill the obligation of **importers** under the MDR.
- Those who produce devices are **considered manufactures of medical devices or manufacturers of custom-made devices.**
- Those actors who operate between production and direct supply to the customer may be **assembler, importers or an authorised representative** of a manufacturer. Please note that these actors serve multiple purposes and therefore different obligations under the MDR.

Since opticians and optometrists are responsible for dispensing a visual aid to consumers/clients, they need to fulfil the obligations of a distributor. This does not mean that this becomes their job title or classification at national level**,** rather it defines the requirements to be fulfilled under the MDR, which are stipulated in Article 14 of the MDR.
However, depending on the product, it could be that they need to fulfil other roles too. In some circumstances, the role of manufacturer could come into consideration, however this is not typical nor recommended because it would translate into a wide range of complicated and costly obligations, such as the application of UDI (Unique Device Identifier) requirements and clinical evaluations. Usually, the optician or optometrist sources frames and glasses from an industrial manufacturer, who is responsible for fulfilling the manufacturers' requirements.

*Being classified as custom-made device manufacturer would also require some additional obligations to be fulfilled. Key requirements include:*

- Implementation of a risk management system
- Clinical assessment and technical documentation
- Registration as a manufacturer of CMD and appointment of a responsible person with legal liability
- Post market evaluation
- Proactive monitoring of products in the marketplace
- Free sampling by authorities

An example falling into this category would be if an optician/optometrist manufactures a corrective spectacle frame and/or an ophthalmic lens from scratch out of the necessary raw materials or uses non-CE marked components such as ophthalmic lenses or spectacle frames.

Not all of these responsibilities were deemed feasible or appropriate by Member States for optometrists and opticians, who are often SMEs (e.g. the clinical assessment and technical documentation, post market surveillance and proactive monitoring of products in the market place). In addition, custom-made devices cannot be mass produced, which posed a legal issue in the way the MDR has been interpreted and which was considered necessary to be in line with internationally agreed guidance. In particular the International Medical Device Regulators Forum (IMDRF) document of 2018: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181018-pmd-definitions-n49.pdf.

It is however clear, and **ECOO strongly emphasises, that opticians and optometrists are fulfilling a more important role than a mere "distributor" (an MDR terminology and not the classification of a profession) when fitting prescription spectacles or contact lenses** which is why national provisions or legislation is in place, or should be developed, to stipulate any specific requirements that are of relevance to the national context and that may go beyond these provisions.

**Recommendation to ECOO members**:
Check what national laws exist or have been drawn-up to meet the MDR requirements and ensure a product requirement interpretation does not affect the status of the profession itself. In this context, bear in mind that the MDR has been designed for consumer safety. The legal, liability and vigilance safeguards are to protect the consumer. The eye care professionals are the point of contact between the product and the consumer/patient. In countries that have no national law in place, the EU legislation would be the only applicable legal reference.

# CORRECTION SPECTACLES CLASSIFIED AS ADAPTABLE MEDICAL DEVICES

Member States made use of the IMDRF document referenced above to solve the dilemma of corrective spectacles (composed of a frame and an ophthalmic lens – both being medical devices separately) which can be interpreted as neither a custom-made device nor a medical device in its own right.

Instead, the terminology of "adaptable medical device" has been taken from the IMDRF document and a non-binding Q&A document has been agreed by all Member States: https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-3_en.pdf

***To note:*** The Q&A document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in the document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

The fact that Member States agreed the document suggests a compromise for a harmonised approach has been reached and the provisions will be largely followed at national level. It can however be expected that some Member States take this position further or interpret it in slightly different ways depending on how national provisions for opticians/ optometrists correlate with the MDR.

**Recommendation to ECOO members:**
ECOO members should contact their national authorities to enquire as to how the Q&A will be used, translated and interpreted.

An "adaptable medical device" has been defined in the Q&A as follows:
*Adaptable medical devices are mass-produced medical devices which must be adapted, adjusted, assembled or shaped at the point of care, traditionally by a healthcare professional, in accordance with the manufacturer's validated instructions to suit an individual patient's specific anatomo-physiologic features prior to use.*

The Q&A also stipulates that a person who adapts, adjusts, assembles or shapes an adaptable medical device for a particular patient is not regarded as a manufacturer but a distributor. This is however only valid as long as the adaptation, adjustment, assembly and shaping does not modify the intended purpose of the device or changes the compliance with the applicable requirements.

It is important to note that an optician/ optometrist needs to use CE marked components, to create an adaptable medical device. If they however use non-CE marked components they become responsible as a manufacturer of a custom-made device. Opticians/optometrists must follow the instructions for use provided by the manufacturer of a CE marked device in the interest of their own liability (see below). If they do not, then they take on the responsibility of a manufacturer.

The definition above refers to "traditionally a healthcare professional", however the MDR states that any person authorised by national law is included in this. It is therefore up to Member States to establish who qualifies as an authorised person. Opticians and optometrists are therefore not excluded from this by EU-law. **(Note: ECOO currently seeks to gain clarity from the European Commission on a possible ambiguity in the phrasing of the Q&A).**

# OBLIGATIONS OF A DISTRIBUTOR UNDER THE MDR

The obligations of a distributor are stipulated in Article 14 of the MDR.

*The following provisions needs to be checked to ensure that the:*

- CE marking has been applied
- EU declaration of conformity of the device has been drawn-up by the manufacturer (note: this also applies to additional pieces such as the nose pads. They are not necessarily added to every device but the manufacturer needs to keep these readily available)
- Information to be supplied by the manufacturer has been received
- UDI has been assigned by the manufacturer (note for Class I products, this will come into effect in 2025)

The optician and/or optometrist does not need to check every single device but rather choose representative and documented samples. The MDR does not give guidance on the size of the sampling, however typically the circumstances such as length of cooperation with the manufacturer and knowledge about possible risk factors should be considered.

## *CONFORMITY ASSESSMENT*

Where there is reason to believe that a device is not in conformity with the MDR, it should not be placed on the market and the manufacturer needs to be informed. If there are reasons to believe that the device presents a serious risk or is falsified, then the national competent authority needs to be notified.

Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available need to forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and/or the importer (see below). They also need to keep a register of complaints, of non-conforming devices and of recalls and withdrawals, keep all parties involved informed and provide them with any information upon their request.

**Note:** When dealing with patient records and transfer of information between parties, opticians and optometrists need to ensure proper arrangements relating to personal data collected, stored, processed or disposed of are drawn-up and are in compliance with the requirements of the General Data Protection Regulation 2016/679 (“GDPR”).

As conformity under the MDR can be far reaching, optometrists and opticians should consider if a device fulfils its purpose under normal conditions of use and whether any risk to the customer/patient from the use of the device can safely be excluded. For opticians and optometrists conformity issues would typically relate to spectacle lenses, spectacle frames and/or contact lenses e.g. a lens cannot be fixed to the spectacle frame; the ophthalmic lens has no corrective effect, the coating loosens or the spectacle frame causes an allergic reaction,

## *LIABILITY OF OPTICIANS AND OPTOMETRISTS*

Liability rests with the optician and optometrist, and not with the manufacturer, if a complaint is the result of their work or service. For example, if the customer claims an incompatibility of the glasses due to a grinding mistake or wrong refraction measurements. This is not the type of information that needs to be kept on register as per the non-conformity requirements of the MDR. Nevertheless this should be documented in the patient record for good practice.

**Recommendation to ECOO members:**

- In communications with patients, opticians and optometrists should stay within the supported indications and claims of the manufacturer e.g. replacement frequency for contact lens fitting.
- Modifying rigid contact lenses for example, should only be done in accordance with the manufacturers' validated instructions for use for the eye care professional. It is advisable to document the changes so as to have a record in case of an issue and to showcase a standard of service as the liability shifts to the eye care practitioner.
- Dispensing an instruction for use leaflet (in paper or electronically) for the respective contact lens will offer some protection in case of a liability law suit.
- If the manufacturer excludes the adaptation of a rigid gas permeable contact lens, then the eye care practitioner has to assume the role of a manufacturer when modifying the contact lens.
- It is also advisable to Inform the patient of the fact that the item sold is a medical device and requires the services of an eye care professional.

## *STORAGE AND TRANSPORT CONDITIONS*

Distributors also need to ensure that storage or transport conditions comply with the conditions set by the manufacturer, as soon as the device is under their responsibility.

## *IMPORTED DEVICES FROM OUTSIDE OF THE EU*

For imported medical devices, when the manufacturer is based outside the EU, an authorised representative/company, which is based in the EU and which fulfils the obligations of a manufacturer of medical devices is required. This authorised representative can also be the "importer", i.e. the person/company that first places the medical device on the EU market. However, these may also be three separate entities, i.e. the manufacturer, authorised representative and importer, who each have to fulfil the obligations under the MDR before the optician receives the product.

*When receiving an imported medical device, in addition to the above requirements, the optical/optometric business needs to check:*

- the name of the authorised representative and the importer, their registered trade name or registered trade mark,

- if applicable, a registered place of business, and
- the address at which the authorised representative and the importer can be contacted.
- These details, which may be on an additional label, shall not obscure any information on the label provided by the manufacturer.

### *COOPERATION REQUIREMENTS*

Opticians and optometrists have an obligation to cooperate with the competent authorities and to provide them with any information and documentation that demonstrates the conformity of a device. They need to grant free samples or access to the device as needed.

# PRESCRIPTION REQUIREMENTS

The MDR states that it does not affect national law concerning the organisation, delivery or financing of health services and medical care, such as the requirement that certain devices may only be supplied on a medical prescription, the requirement that only certain health professionals or healthcare institutions may dispense or use certain devices or that their use be accompanied by specific professional counselling.

This means that it is up to Member States to define who can issue a prescription and for what purposes. The Q&A document simply states:

> *A written prescription must be issued by a qualified person authorised by national law. At minimum, it should contain:*
>
> - the name of the patient (or pseudonym if relevant),
> - specific design characteristics made by the authorised person which are unique to the patient's anatomic-physiological features and/or pathological condition.

**Recommendation to ECOO members:**
Ensure the prescription provisions are well defined and respected at national level.
The MDR does not affect the national laws on this matter.

# HOW IS EUDAMED RELEVANT TO OPTICIANS/OPTOMETRISTS

The EUDAMED is the European database on medical devices, which is expected to be fully functional as of 2024.

Class I medical devices, such as corrective spectacles, only need to be UDI complaint from May 2025 onwards. Applying a UDI is the responsibility of the manufacturer. The eye care practitioner will be able to document the UDI number in the records of the corrective spectacles.

# DISCLAIMER

This guidance document has been drawn-up by ECOO to inform its members of the requirements of the MDR. ECOO is not liable for any interpretations, translations or deviations from the intended guidance taken by national authorities or members themselves. In case of doubt, legal advice should be sought for the national context.

Further guidance and clarifications are expected from the EU-level.
This guidance document will be updated as these become available.

ECOO
European Council of Optometry and Optics