Attachment 1 - Frequently Asked Questions

What does CE mean?
CE means Conformité Européenne. When this mark is displayed on a product or its packaging, it means that the product complies with the rules applicable to the product within the European Economic Area (EEA, i.e. the European Union, Switzerland, Liechtenstein, Norway, and Iceland) and that the manufacturer is in control of the product and the processes associated with the product throughout the lifetime of the product. Please note: the CE mark is not a quality mark.

Which rules apply to frames?
A frame is a functional part of a pair of glasses, since the spectacle lenses have a medical purpose (helping the user to improve his/her vision) and are therefore covered by the Medical Device Regulation, the MDR. Because spectacle lenses cannot function without the frame, the same legislation applies to frames.

What is a Medical Device?
Medical devices (MD) are products that are used in the prevention, diagnosis, treatment and support of an illness or disability/disability.

What does MDR mean?
The MDR is a European Regulation that lays down new rules on medical devices and is short for 'Medical Device Regulation'. The official designation of MDR is: (EU) MDR 2017/745.
With this legislation, very specific and clear rules have been implemented to ensure the safety of medical devices.

What does CE mean when it is printed on a frame?
This means that the manufacturer meets all the requirements of (EU) MDR 2017/745: the medical device has demonstrated **safety** and **efficacy** with regard to:

- Use of the product.
- The manufacturing process (including the controls/checks of this manufacturing process, even though this manufacturing process may be partly carried out by another party on behalf of Dutz Eyewear).

The manufacturer thus assumes responsibility for the entire process, including the placing of the frames on the market and controls/checks that must be carried out during marketing.

Role in the chain
Dutz Eyewear BV will assume the role of 'legal manufacturer' (LM) starting January 2024 and will also identify as a LM on the packaging.

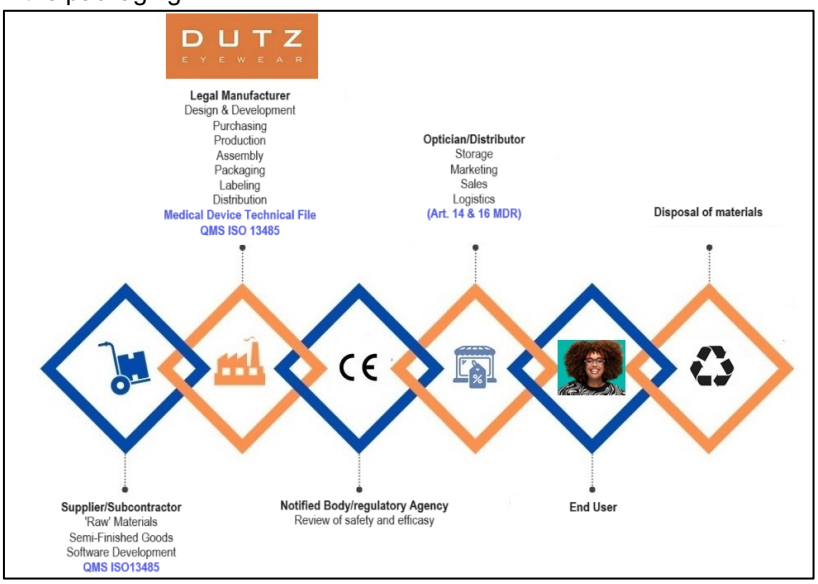

Figure 1: the role of Dutz Eyewear in the chain.

How can Dutz Eyewear BV be identified as a 'legal manufacturer' on the packaging?
Starting January 2024, Dutz Eyewear BV will be listed on the packaging as follows:

Dutz Eyewear BV
Angelenweg 162
5349 TC Oss, The Netherlands

What does it mean that Dutz Eyewear BV is acting as Legal Manufacturer/manufacturer?
From a legal point of view, as a Legal Manufacturer Dutz Eyewear BV takes full responsibility for:

- the production process from design, (purchase of) raw materials, production, assembly, packaging, labelling up to and including storage & transport.
- the sales, marketing, and distribution process.
- the product on the market, including after-sales activities, complaint/warranty handling and other feedback from the market and the disposal of materials that have reached the end of their lifetime.

Dutz Eyewear BV has a certified Quality Management System according to the ISO 13485 standard, demonstrating that Dutz Eyewear BV has full control over the entire process during the lifetime of a frame, including the outsourced activities. The production partners are therefore tested annually by Dutz Eyewear by means of interviews, audit visits and written questionnaires. A copy of the ISO certificate can be provided upon request.

A Technical File has been created in which the design, manufacture and operation of the frames are described. With this file, it is fully demonstrated that the frames produced by Dutz Eyewear BV are 'safe' and 'effective' for use. In addition, the frames are officially registered as a Medical Device.
The 'Declaration of Conformity' provided by Dutz Eyewear BV is a confirmation that the frames of Dutz Eyewear meet all these conditions.

What is ISO 13485?
The ISO 13485 standard specifies the requirements for a 'quality management system' for an organisation, which must be able to demonstrate its ability to provide medical devices and related services (including outsourced processes) that constantly meet customer requirements and applicable legal requirements.

What is a Declaration of Conformity?
A Declaration of Conformity (abbreviation: 'DoC') is a legal, mandatory document that Dutz Eyewear, as the Legal Manufacturer of a medical device, must sign and provide to Opticians. Dutz Eyewear hereby declares that the frames comply with EU requirements and that Dutz Eyewear is fully responsible for complying with applicable EU legislation.

Products that are intended for sale and use in the European Union or European Economic Area (EU/EEA) must comply with legal requirements on safety, health, and the environment. As legal manufacturer/brand owner, Dutz Eyewear BV is responsible for ensuring that our frames comply with all these requirements.

Although there are no specific rules for ‘origin marking’ for medical devices, when applied the origin details must refer to the country in which the product has undergone 'its last substantial processing', meaning where value was added [1].

Dutz Eyewear’s frames are a functional part of the Medical Device ‘pair of glasses’ (which is created when the Optician inserts spectacle lenses to Dutz Eyewear’s frames). Therefore, Dutz Eyewear adds important part of value to this MD by ‘designing the frames’ by our own team at Dutz Eyewear, determining the choice of raw materials, having full control of the production process at our partners, performing incoming checks, and having full control of storage, labelling and release of the frame for distribution in the market.
All possible risks in the process are thus identified and controlled by Dutz Eyewear.

[1] Regulation (EU) No 952/2013 and its additional regulations.

Information from the market: complaint handling and feedback
Dutz Eyewear BV has specific complaint and warranty conditions that must be followed by the opticians. For more details: Dutz Service.

A ‘complaint’ is considered any form of expression of dissatisfaction with a product, person or service. Complaints may arise during normal use of the frames, but also due to so-called 'abnormal use' or 'misuse'.

'Feedback' includes any response to Dutz Eyewear's frames, both positive and negative. Feedback can be provided verbally, but also in writing in the form of an e-mail, review on a website, etc.

Because Dutz Eyewear BV will be responsible as a LM starting January 2024, all information regarding products on the market must be registered by Dutz Eyewear. When you, as an optician, receive this information, it is therefore very important that it is passed on to Dutz Eyewear BV immediately. You can report complaints/feedback through mailto:service@dutzeyewear.com.

If you have any questions, you can always reach us by e-mail:mailto:info@dutzeyewear.com.