SWISS MEDTECH

Information for Swiss opticians

Regulatory requirements for optical frames

Guidance

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This document was written in collaboration with The Tao of Excellence GmbH

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endorsed by

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Content

Management summary

This document describes the regulatory requirements for optical frames, which are considered as medical devices according to the Swiss Medical Device Ordinance. It offers guidance to opticians engaged in the role of manufacturer, importer and distributer in Switzerland. The document emphasizes the essential requirements and verification activities that are integral to ensuring compliance and maintaining the safety and effectiveness of these medical devices.

Optical frames like other medical devices are subject to maintenance and repair. This document includes an overview of the maintenance and repair tasks that opticians might do. The approach on the maintenance and repair activities in sync with the quality and regulatory requirements is addressed to ensure continued intended product performance and patient safety. A comprehensive checklist is provided at the end summarizing the verification obligations of the opticians in the roles of importers and distributors.

1 Introduction

Optical frames are used to hold prescription lenses for vision correction in place. They are considered as medical devices under the Swiss Medical Devices Ordinance (MedDO) if their intended purpose is to correct or compensate for vision impairments.

Frames for sunglasses and frames for safety eyewear with the intended purpose of eye protection without correcting vision are regulated as personal protective equipment (PPE) under the Personal Protective Equipment Regulation (PSAV). However, they are also considered as medical devices when the PPE has prescription lenses fitted in and therefore must also meet the regulatory requirements for medical devices.

Optical frames must be fitted to accommodate the patient's anatomy of the head to achieve the intended purpose of the vision correction. As they can be in use for a prolonged time, the frames may wear out or become damaged and may consequently require maintenance or repair.

This guidance intends to provide clarification on the regulatory requirements for maintenance and repair of optical frames by opticians in Switzerland.

2 Scope

The guidance applies to:

- optical frames, which are considered as class I medical device according to the MedDO.
- frames for sunglasses and safety eyewear, fitted with prescription lenses for vision correction which are considered as class I medical device according to the MedDO.
  Note: Though the primary mode of action for such frames is personal protection, the device is subject to both the applicable regulatory requirements of MedDO and PSAV, unless specifically excluded.

This guidance applies to both frames and prescription lenses, which are also considered as medical devices. This guidance does not apply to safety eyewear as they do not allow any repair as per PSAV.

3 Legal basis and definitions

- MedDO: Swiss Medical Devices Ordinance 812.213 (as on 01. November 2023)
- MDR: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices
- PSAV: SR 930.115 (Verordnung über die Sicherheit von persönlichen Schutzausrüstungen - PSAV).
- PPER: EU REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on personal protective equipment (PPER).
- Information sheets issued by Swissmedic. E.g., MU600_00_016: obligations economic operators
- The definitions, terms and primary references of this guidance are used as per MedDO. If not specifically available, they are used as per EU MDR 2017/745.

- Certified opticians and optometrists are both considered under the term ‘opticians’ throughout this guidance. The simplified pronouns ‘he/his’ are used to include all genders.
- Optometrists are considered as healthcare professionals while the wearer of the frame is the patient.
- Optician’s stores are healthcare facilities as their purpose is to provide care or treatment for clients and patients. In contrast, a hospital is a healthcare institution in which inpatient treatments are provided.

4 Roles and obligations of an optician under MedDO

The optician who makes optical frames available to the patient is an economic operator in the supply chain. He can be a natural or legal person and is not explicitly ‘designated’ as economic operator, but his role arises from the activity that he assumes. Roles and obligations for economic operators were introduced to the MedDO in May 2021. An optician can assume more than one role dependent upon the activities performed by the optician.

Note: The following sub-chapters are designed to interpret the roles specifically for the opticians. Please refer to the corresponding chapters of the MedDO to be fully compliant to the respective roles.

4.1 Optician as a distributor

The optician takes on the role as a Swiss distributor when he buys the optical frames from an economic operator domiciled in Switzerland (Manufacturer and / or importer) and makes them available in his store. The Swiss distributor has regulatory obligations for any supply of optical frames for distribution and use in Switzerland during a commercial activity, whether in return for payment or free of charge.

A checklist is provided in Section 6 for the points to be verified before making the optical frames available.

Example: The optician store ‘X’ in Niederbipp, Switzerland takes on the role of a Swiss distributor by buying a specific frame from ‘Y’ in Zürich, Switzerland.

4.2 Optician as an importer

The optician takes on the role as a Swiss importer when he buys the optical frames from an economic operator outside of Switzerland and makes them available in his store. The Swiss importer is therefore the first economic operator within the supply chain domiciled in Switzerland. He is responsible for the first making available of the optical frames in Switzerland and as such places the optical frames on the Swiss market. The Swiss importer has regulatory obligations for any supply of optical frames, for distribution, use in Switzerland in the course of a commercial activity, whether in return for payment or free of charge.

The importer has to request for a Swiss Single Registration Number (CHRN) from Swissmedic within three months of his first placing on the market. They must also indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trademark, their registered place of business and the address at which they can be contacted, so that their location can be established.

A checklist is provided in Section 6 for the points to be verified before placing the optical frames on the market.

Example: The optician store 'X' in Niederbipp, Switzerland takes on the role of a Swiss importer by buying a specific frame from 'A.' in München, Germany

4.3 Optician as a manufacturer

The optician is considered a manufacturer for the purpose of the regulation and takes on the obligations when he does any of the following:

(a) makes available on the market a device under his name, registered trade name or registered trademark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements.

Example: The optician store 'X' sells optical frames under his own brand 'Optimal' without identifying the legal manufacturer 'B.' on the label. He, the optician store "X" takes on obligations of the manufacturer.

(b) changes the intended purpose of a device already placed on the market or put into service.

Example: The optician store 'X' buys optical frames intended to hold prescription lenses. However, he sells them for safety eyewear with prescription lenses. He is changing the intended purpose and therefore takes on obligations of the manufacturer for MDR and PPER.

(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

Example: The optician store 'X' uses very cost-effective material to replace broken original temples, which differs from the legal manufacturer's recommendation. This might compromise the Strength or biocompatibility of the optical frames. He takes on obligations of the manufacturer.

Example: The optician store 'X' assembles the frames according to the manufacturer's description. He also adjusts the temples to fit an individual patient's head, maybe shorten the length by cutting the temples and remounting the ear tip. The adjustments do not change the intended purpose, nor do they affect the compliance of the device. He does not need to take on the obligations of the manufacturer.

Example: The optician store 'X' inserts prescription lenses on a safety goggle that is already sold to a customer. The optician in this case is modifying the PPE and therefore assumes the responsibility of the manufacturer of the PPE.

The intended purpose of a medical device is given in the EU Declaration of conformity (DoC) and / or instruction for use (IFU), a document that is available to the distributor and importer.

The obligations of a manufacturer clearly go beyond the obligations of the distributor or importer. A thorough assessment of compliance is recommended.

4.4 Incident reporting

The incident reporting obligations apply to any regulatory role. This section aims to clarify the term «incident» for opticians.

An «incident» in the MedDO means:

- any malfunction or deterioration in the characteristics or performance of a device made available on the market,
- including use-error due to ergonomic features,
- as well as any inadequacy in the information supplied by the manufacturer,
- any undesirable side-effect.

An incident is an event that occurs after the device is sold to the customer. Quality issues detected before the sale are not considered as patient related and are therefore not handled as incidents. The categorization of the incident is the responsibility of the manufacturer.

The optician must immediately forward to the manufacturer and its CH-REP (authorised representative), complaints or reports from healthcare professionals, patients or users about incidents related to the device which they have sold.

Examples:

- *A frame advertised as being made from titanium shows early signs of corrosion.*
- *A frame advertised as allergy free create skin lesions on the nose and the ears of the user.*
- *Metal inlets in the frame fall off or exhibit signs of corrosion.*
- *The color of the lenses has gradually changed over time.*
- *Decorative items such as crystals, logo fall off from the frames.*

5 Maintenance and repair

5.1 Definition of maintenance and repair

Routine maintenance activities that do not require a specialist's expertise are not considered as maintenance activities in the context of this guidance document. These activities may also be performed as a walk-in service at the optical stores without a typical one to one client relation. Activities that are performed for fitment of the frame to the patient's face / head and mounting lenses as intended by the manufacturer are also not considered as maintenance.

Examples not considered 'Maintenance' as per MedDO:

- *Cleaning of frames and lenses (including brief removal and reinsertion in the frame)*
- *Tightening of the screws*
- *Exchanging of nose pads*
- *One-to-one replacement of screws and ear tips.*
- *Heating of frame to adjust to the face/head of the client or to mount lenses.*

‘Maintenance’ refers to the upkeep of a medical device to ensure that it continues to function as intended by the manufacturer. It must be carried out in accordance with the manufacturer's instructions, if available.

Examples of Maintenance:

- *Replacement of screws and ear tips, which may impair the function of the frame.*
- *Adjusting length of temples e.g., cutting temples and remounting original ear tip to fit frame to the head of the client.*
- *Changing the shape of a rimless frame to adapt to the face of the client.*
- *Replacing lenses on existing frame – e.g. new lenses are mounted into the frame (by heating – acetate frame) or opening/closing the screws (metallic frames).*
- *Adding prescribed foils on lenses (for eye treatment).*

‘Repair’ refers to the restoration of a medical device to its original intended condition. It may not fully restore the original features, but must not compromise the safety, performance, and clinical performance of the device, and must be done by qualified personnel. It is therefore in the responsibility of the person performing the repair to ensure that the device continues to meet all relevant safety and performance requirements after the repair.

Examples of Repair:

- *Soldering / welding / gluing of broken parts of the frame*
- *Exchange / Repair of hinges*
- *Recoloring the frame*
- *Applying anti-allergy coatings*
- *Replacement of spare parts, such as the temples*
- *Fitting lenses into a new frame (if the original frame is broken)*
- *Polishing flaked areas on the edge of the lens*

It is in the responsibility of the operator performing the maintenance or repair to ensure that the device continues to meet all relevant safety and performance requirements after the operation. It is therefore important that he understands the corresponding regulatory requirements. It is recommended that a well-defined documented procedure for maintenance and repair of the optical frames is available, and that the operator is trained on it.

5.2 Regulatory requirements for maintenance and repair

As the maintenance and repair of optical frames / lenses could potentially alter the safety and performance of the frames / lenses, the regulatory requirements are translated to optician’s activities as follows:

- The maintenance and repair of optical frames must not compromise the safety and stability of the frames and holding the prescription lenses in place.
- A documented procedure is available and defines maintenance and repair. It includes checking the intended purpose, consulting the manufacturer’s instructions and other documentation available and defining the material to be used and/or avoided.
- Operators performing the maintenance and repair are trained on the procedure. The training is documented.
- The optician store keeps records of the maintenance and repair. In case of repair the identification information of the optical frame / lenses, the operator, the date, the nature of the repair and the spare parts are recorded (e.g. in the customer dossier) in order to assure the traceability.

Evidence of the compliance on regulatory requirements could be requested by Swissmedic or the cantonal authorities.

5.3 Quality management system for opticians

The MedDO requires the performance and documentation of various activities that must follow the principles of a quality management system and be properly organized and documented and take into account the risks inherent to the medical device. The requirements are limited to the obligations as a manufacturer (Section 4.3) and the specific activities around maintenance and repair (Section 5.2).

As per the focus of this guidance and not including the requirements for the manufacturer's obligations, the following components are recommended for implementation and upkeep:

- Assess your economic role including all your activities. Register for your CHRN as importer and/or CH-REP. Further information on CH-REP is available here.
- Define and document how you ensure compliance in your economic role.
- Define and document the communication along the supply chain based on your economic role. Make sure you know the corresponding contacts. Define responsibilities to collaborate with supply chain and authorities.
- Document the evidence of training of operators.
- Check and store market related documents as evidence of compliance: declarations, certificates, CH-REP / importer identification as applicable.
- Ensure and document traceability of all medical devices forward and backward in the supply chain: Where you have bought the device and to whom you have sold it.
- Document the procedure on maintenance and repair. Ensure that the operators performing maintenance and repair have access to the instructions.
- Ensure and document traceability as part of repair.
- Document storage and transport of medical devices. Define the conditions of storage and transport and make a risk assessment if necessary.
- Dependent on your regulatory role, keep a register on information from market: complaints, non-conforming devices, recalls and withdrawals.
- Ensure a process of communication with manufacturer, CH-REP and Swissmedic for vigilance.

6 Appendix: Checklist

Example of Checklist to review the primary packaging and documents of optical frames.

1	CE	**CE marking** on label and product	☐ OK ☐ Not OK
2	MD	**Medical Device**	☐ OK ☐ Not OK
3	LOT	**Lot number and barcode** or other number for traceability	☐ OK ☐ Not OK
4		**Name and address of legal manufacturer**	☐ OK ☐ Not OK
5	REF	**EAN code and barcode or QR Code** Code has to be functional.	☐ OK ☐ Not OK
6	**Description of model** brand, model code, colour, size (ISO 12870)		☐ OK ☐ Not OK
7	CH REP	**CH-REP incl. address** CH-REP: text (3 languages) or icon for legal manufacturers outside CH on product itself from 07.2023 on (possibilities: on sticker, directly printed on polybag or on the IFU). until then on accompanying document also allowed.	☐ OK ☐ Not OK
8		**CH Importer incl. address** Importer: text (3 languages) or icon for legal manufacturers outside CH on product itself or on accompanying document (E.g. Invoice)	☐ OK ☐ Not OK
9		**Instruction for use optical frames** in 3 languages FR/DE/IT If provided by legal manufacturer.	☐ OK ☐ Not OK
10	UDI	**UDI Unique Device Identifier** Not yet mandatory	☐ OK ☐ Not OK
11	DoC	**EU declaration of conformity** - DoC available on web or received per email and filed - DoC compliant with EU MDR	☐ OK ☐ Not OK
For Importers only			
12	Check Mandate	**Verify the CH REP** Verify if the CH-REP is mandated – check with manufacturer and on label Is he registered at Swissmedic: *https://opendata.swiss/en/dataset/mep401-chnr-actors* *https://www.swissmedic.ch/swissmedic/en/home/medical-devices/medizinprodukte-datenbank/chrn-swiss-single-registration-number.html*	☐ OK ☐ Not OK
For Distributors only			
13	Check Mandate	**Importer** Verify if the Importer is registered at Swissmedic: https://opendata.swiss/en/dataset/mep401-chnr-actors https://www.swissmedic.ch/swissmedic/en/home/medical-devices/medizinprodukte-datenbank/chrn-swiss-single-registration-number.html	☐ OK ☐ Not OK

Example of Checklist on the obligations of **Importers** and **Distributors of optical frames:**

1	Register as Importer	Register as importer at Swissmedic: *https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/pflichten-bevollmaechtigte.html*
2	Check Label	Check labeling: For importers 100% check For distributors sampling only
3	Register Complaints	Keep register of complaints and nonconforming products and provide to the legal manufacturer if requested (post-market surveillance).
4	Register Recalls	Keep register of recalls and withdrawals and provide it if requested.
5	Communicate incident	Forward complaints and reports on incidents to manufacturer, CH-REP and importer (if in the role of distributor).
6	Storage Transport	Secure that storage and transport conditions do not harm the product, as per the conditions defined by the manufacturer.
7	Cooperate	Cooperate with the manufacturer, authorised representative, designated body and competent authorities and provide information needed to support in the event of a mitigating action such as a recall.

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02	25.03.2024	Deepa Rajagopalan (The Tao of excellence), Bettina Herrmann (meditec Consulting GmbH)	Jasminka Roth (The Tao of excellence)	Daniel Delfosse (Swiss Medtech)	Chapter 4, Sec. 5.3 and Checklist adapted for clarity; Sec. 4.4 on incident reporting added, Pt. 5 (communicate incident) added in Checklist