

OPTICAL FRAMES

1. Name

This manual has been developed for the optical frames, a medical device manufactured by Prostaf sp. z o.o. sp.k. It covers the following models:

- BERGMAN
- NORDK by BERGMAN
- CHILI by BERGMAN
- ORANGE by BERGMAN

2. Manufacturer

The optical frames covered by this manual have been manufactured by:
Prostaf sp. z o.o. sp.k., ul. Jasielska 7a, 60-467 Poznań

3. Intended use

Optical frames, a medical product, is one of the elements of another medical product, i.e. corrective glasses. The manufacturer of frames for glasses supplies them to opticians' shops, where the optometrist, after examining the patient and choosing appropriate corrective lenses, mounts adjusted glasses in them. The function of an optical frame is to hold the corrective lenses in position, so that the lenses can provide the required vision correction.

Prostaf optical frames are made of metal or plastic. All materials used are dedicated to the manufacture of this type of product.

Optical frames meet the requirements of the following standards:

- PN EN ISO 14971:2020
- PN-EN 62366-1:2015-07/AC:2018-08
- PN-EN ISO 12870:2018-06
- PN-EN ISO 8624:2021-01

Optical frames are delivered to the optician's shops in a pre-shaped form. This means that the frame components for attaching the corrective lenses are already preformed. The temples, on the other hand, are preformed but need to be customised for each individual patient. The materials used to make temples are polymers or metals, which are commonly used for this purpose. Therefore, moulding them should not be problematic.

If you have any further questions or need to replace damaged/lost components, please contact Prostaf sp. z o.o. sp.k.

4. Warnings

The product should be stored in a case to that protects it from mechanical damage.

The product should be maintained and kept clean. Clean the product with a soft cloth. If the product is very dirty, rinse it gently with water and then dry it. Finished optical - frames with corrective lenses - should be kept in their case.

The product should not be cleaned with strong chemicals as this can damage it and cause irritation or allergies in the patient.

If discolouration and/or damage to the frame surface is found to have occurred as a result of improper care of the product, contact the optician's shop where the product was purchased immediately.

5. Contraindications

- If you develop an allergy or skin irritation after contact with the product, consult your doctor.
- Do not attempt to fit the product yourself. This should be done by a professional optician only.
- If any part of the product is lost or damaged, consult your optical store to see if the frame can be repaired.

NOTE:

Any serious incident related to the use of the spectacle frames should be reported immediately to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products:

- e-mail: incydenty@urpl.gov.pl
- registered letter or courier service: al. Jerozolimskie 181c, 02-222 Warszawa
- fax: 48 22 492 11 29

6. Service life

Optical frames can be used for as long as corrective lenses can be correctly fitted in them and they fulfil their function.

7. Date

28 March 2022