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When selling medical devices, the fitter, hereinafter referred to as the optician, is obliged to inform the end user, hereinafter referred to as the spectacle wearer, of any restrictions on use, preferably in written form. Convince your customers with your expertise by pointing out relevant restrictions on use during your individual and personal consultation.

You can find important information on Rodenstock lenses at any time at <https://www.rodenstock.de/de/de/instructions-for-use.html>

## 1 Intended use

### 1.1 General information

- Spectacle lenses are used to correct visual defects and error of position of rest.
- Spectacle lenses are Class 1 medical devices and have been covered by Regulation (EU) 2017/745 on medical devices since 26 May 2021 and meet the corresponding requirements. The proof of conformity is based in some criteria on the fulfilment of the standard EN ISO 14889 "Ophthalmic optics - Spectacle lenses - Basic requirements for raw-edged finished spectacle lenses" and the applicable standards of the EN ISO 8980 series at the time of sale. All ophthalmic lenses in the Rodenstock product catalogue are currently tested in accordance with EN ISO 14889:2013 + A1:2017 and EN ISO 8980-1:2017, 8980-2:2017, 8980-3:2022 and 8980-4:2006 and are marked with the CE label on the lens bag.
- According to standard EN ISO 7944:1998 "Optics and optical instruments - Reference wavelengths", both the refractive index and the vertex power of spectacle lenses refer to the e-line of mercury (546.07 nm).
- To ensure proper and professional optical care, reference is made to the applicable national guidelines for ophthalmic optics and optometry, e.g. the work and quality guidelines for ophthalmic optics and optometry of the ZVA (Germany) and the ECOO guidelines for optometric and optical services in Europe.
- Spectacle lenses are designed for everyday use in normal environmental conditions (temperature and humidity), but not for extreme conditions, such as in a sauna or in a car parked in the sun.
- Spectacle lenses are intended for use in pairs in a spectacle frame, i.e. as a combination of right and left lens in front of the wearer's eyes.
- Spectacle lenses are not usually worn in combination with contact lenses if they already correct the same customised refractive error.
- Spectacle lenses are calculated so that the ambient medium on the eye and object side is air ( $n=1.0$ ). For the best vision under water, e.g. when swimming or diving, the refraction data must be converted.
- Minimum visual performance requirements apply for the issue of a driving license, which must be achieved with or without visual aids (glasses or contact lenses) by means of an official driving license vision test. In case of doubt, the applicant must be examined by an additional medical Center.

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- If a visual aid is required to pass the eye test, this will be noted on the driving license. The applicable minimum requirements may vary depending on the country. If necessary, find out about the locally applicable requirements.

## 1.2 Lens materials

- Spectacle lenses are available in various materials and refractive index.
- The higher the index of refraction, the thinner the lens can be made and the lighter the lenses will be.
- At the same time, the lower the refractive index, the lower the dispersion (higher Abbe number) in a corrective lens and therefore the "colour fringe" perceived as disturbing in peripheral vision at the edge of the spectacles. This effect is particularly visible at high powers.
- Rodenstock plastic lenses are available in the refractive indices 1.50, 1.53 (Trivex), 1.59 (polycarbonate), 1.60, 1.67 and 1.74.
- Photochromic lenses made of plastic are available for refractive indices 1.54, 1.60 and 1.67, in which a photochromic effect is triggered by the UV radiation of sunlight.
- UV protection is defined in the ophthalmic lens standards up to a wavelength of 380 nm. All lenses in the Rodenstock product catalogue meet this standard requirement. More extensive protection against visible radiation, such as the common term "UV400", is not standardised. In order to describe the spectral transmission of spectacle lenses in the UV and near-UV visible range, the definitions of EN ISO 8980-3 and 12312-1 have been extended to include wavelengths greater than or less than 380 nm. The information on UV protection in the material and colour overview thus enables a comparison of different materials and finishes. However, an exact comparison with similar specifications from other manufacturers is not meaningful.
- The PRO410 material in indices 1.60 and 1.67 has a light protection that goes beyond conventional UV protection, partially filtering out the potentially harmful short-wave light in the visible range of the spectrum so that it cannot damage the retina.
- Due to the higher density of the material, lenses made of mineral glass are correspondingly heavier than comparable plastic lenses.
- Mineral glasses are offered in the indices 1.52, 1.60, 1.70, 1.80 and 1.90.
- Colormatic products in mineral glass are also available for refractive indices 1.52 and 1.60.
- The satisfaction guarantee for Rodenstock spectacle lenses only applies to the intended use described and when used correctly.

## 1.3 Colouring of spectacle lenses

### Notes on coloured ophthalmic lenses from Rodenstock

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- Coloured Rodenstock lenses are also primarily intended for the manufacture of prescription spectacles and meet the requirements of Regulation (EU) 2017/745 and the EN ISO 14889 standard, which also cover coloured prescription lenses.
- Rodenstock offers a large portfolio of different colourings on plastic lenses. In addition to the UV protection in the material, UV radiation or short-wave light can also be reduced. The most common use is dark-coloured lenses as sun protection. Light colours are mainly used for fashion purposes.

In extension of the EN ISO 8980-3 classification, we distinguish between the following classes for coloured lenses:

1. Single-coloured lenses (solid colours)
2. Lenses which are darker at the top and lighter at the bottom (gradient colours)
3. Multicoloured lenses (bicolour or multicolour tints)
4. Spectacle lenses intended for medical applications. (Medical edge filters)
5. Special colourings from the first 3 classes
6. Polarized lenses
7. Colour layers

### 1. Solid colours

- A wide range of hues and absorptions is possible for the solid colours. These can be found in the relevant product catalogue.

### 2. Gradient colours

- A wide range of colour shades and gradient variants are available for the gradient colourings. These can be found in the current product catalogue.

### 3. Multicolour tints

- These colourings are offered as a supplement to the gradient colourings and are characterised by the depiction of seasonal trends. These can be found in the current product catalogue.

### 4. Medical edge filters


- These are used to provide the spectacle wearer with an appropriate edge filter depending on the indication.

### 5. Special colourings

- Special dyeings are produced at the customer's request according to an existing colour sample, provided this is technically possible, and include the plain, gradient and bicolour dyeing lenses.

### 6. Polarized lenses

- Polarized lenses eliminate light reflections and excessive glare caused by surfaces such as roads, water or snow by only allowing light to pass in one direction. These are also available in combination with other colours.

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## 7. Colour layers


- Colour coatings are coloured coatings on mineral glass. These can be found in the relevant product catalogue.

### Lambda Lens technology

- Rodenstock has developed Lambda Lens technology specifically for coloured lenses. This has created a simple measure of the contrast enhancement of coloured lenses for the customers. All coloured lenses are categorised according to their contrast enhancement:
  - Lower Contrast
  - Mid Contrast
  - Higher Contrast
  - Ultimate Contrast
- Coloured lenses can be coated with hard coatings, anti-reflective coatings and, above all, sun protection lenses with a mirror coating. The available combinations can be found in the current product catalogue.
- If two flat lenses are used for the manufacture of sunglasses, the requirements of Regulation (EU) 2016/425 and standard EN ISO 12312-1 must be observed. When grinding in flat sun protection lenses, EN ISO 12312-1, section 11 "Requirements for the protective function" must be observed. Rodenstock ophthalmic lenses fulfil the relevant requirements.

Filter category	Descriptive label	Usage
Luminance transmittance		
<b>0</b> 81 – 100 %	Light tint sunglasses	Very limited reduction of solar radiation
<b>1</b> 44 – 80 %		Limited protection against solar radiation
<b>2</b> 19 – 43 %	General purpose sunglasses	Good protection against solar radiation
<b>3</b> 9 – 18 %		High protection against solar radiation
<b>4</b> 3 – 8 %	Very dark special purpose sunglasses, very high solar radiation reduction	Very high protection against extreme solar radiation, e.g. at sea, over snowfields, on high mountains, or in desert Not suitable for road use and driving

- Information for spectacle wearers, such as the filter category and any self-tinting or polarising properties of the lenses, can be found in the Rodenstock product catalogue. The description of the filter categories, their values for light transmission and their recommended use can be found in the table below.

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## 1.4 Suitability for traffic and night driving

- A spectacle lens is considered roadworthy if it is suitable for use when driving vehicles in road traffic in accordance with EN ISO 14889 and 8980-3:2022 or 12312-1:2022.
- A spectacle lens is considered suitable for night-time driving if it is suitable for use when driving vehicles at night in accordance with EN ISO 14889 and 8980-3:2022 or 12312-1:2022.

### Hard coatings

- Our plastic lenses are predominantly offered with high-quality hard coatings to ensure excellent scratch resistance in daily use.

### Anti-reflective coatings (including TopCoats)

- Most of our lenses are coated with an anti-reflective coating to reduce annoying reflections.
- Anti-reflective coatings improve the aesthetics of the lenses and ensure a better quality of vision.
- Many of our anti-reflective coatings are finished with a water- and grease-repellent topcoat that makes cleaning the lenses effortless.

### Mirror coatings (including TopCoats)

- For customers looking for a fashionable look, we also offer sun protection lenses with an attractive mirror coating.
- Many of our mirror coatings are also finished with a water- and grease-repellent topcoat, which makes cleaning the lenses effortless.


## 1.5 Transport and storage conditions of raw-edged lenses

- When transporting the lenses and during short-term storage, climatic conditions similar to those typically encountered when wearing glasses in everyday life are permissible, see 1.1 General information.
- The following climatic conditions must be maintained when storing raw-edged lenses for longer periods of time until further processing: Temperatures of 10 to 25 °C and a relative humidity of less than 60 %.

## 2 Restrictions on use & foreseeable misuse

### 2.1 General information

- Spectacle lenses are not suitable as eye protection against mechanical hazards such as impacts and flying sparks.
- As the wearer's refraction data may change, it is advisable to check the refraction data at regular intervals.

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- Due to the lens geometry, limited optically effective diameters are possible with higher myopias.
- Spectacle lenses are generally suitable for driving vehicles and operating machinery. Deviating properties are specified in the Rodenstock product catalogue.
- A spectacle lens is considered roadworthy if it is suitable for use when driving vehicles in road traffic in accordance with EN ISO 14889 and 8980-3:2022 or 12312-1:2022.
- A spectacle lens is considered suitable for night-time driving if it is suitable for use when driving vehicles at night in accordance with EN ISO 14889 and 8980-3:2022 or 12312-1:2022.
- Close-up comfort lenses and lenses used in reading glasses are not roadworthy.
- The usage restrictions "not suitable for night driving" and "not suitable for traffic" are specified for all colours in the colour overview in the appendix.
- For all special designs on customer request that are not included in the Rodenstock product catalogue, it must be assumed that they are not suitable for use for driving vehicles.

## 2.2 Restrictions on the use of coloured lenses

- Coloured lenses are not suitable for looking directly into the sun.
- Coloured lenses are not suitable for protection against artificial light sources, e.g. in solariums.
- All coloured lenses from the current product catalogue are not suitable for protection against sunlight on glaciers. Special glacier goggles are required which have to meet specific requirements.
- Lenses in filter categories 1 - 3 and self-tinting lenses with light transmission values of less than 75% are not suitable for driving at dusk and at night.
- Glasses in filter category 4 are not roadworthy.
- Colours with certain spectral properties are not roadworthy according to EN ISO 14889 and 8980-3 or 12312-1. You will find a detailed overview of colours in the current product catalogue with the identification of colours that are not suitable for night-time driving or traffic.
- In the case of special colours (order codes ending in 00) and colours based on samples (order codes ending in 99), it cannot be guaranteed that they meet the requirements for roadworthiness.
- For special colours or colours according to sample (C00 or C99), no information can be provided on the contrast-enhancing effect.

## 2.3 Additional usage instructions for self-tinting prescription sunglasses

- The light transmission values of self-tinting lenses depend on the ambient temperature, UV radiation and other influences. Our self-tinting lenses are tested under standardised conditions in the laboratory. Under everyday ambient conditions (above 10°C in normal sunlight), they are suitable for road traffic. At low temperatures and in particularly strong sunlight, the light transmission values may be reduced to

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filter category 4. At high temperatures or with reduced solar radiation, the light transmission values may increase accordingly.


- ColorMatic IQ 2 and ColorMatic 3 plastic lenses are suitable for night-time use in accordance with EN ISO 14889 and 8980-3:2022 or 12312-1:2022.
- ColorMatic IQ 2 Sun and ColorMatic 3 Sun lenses are not suitable for night driving.
- Real values of the respective ColorMatic IQ 2 and ColorMatic 3 lenses were determined indoors (brightened) and at 20 °C in the midday sun (darkened).
- The laboratory values are measured according to EN ISO 8980-3:2022 or 12311:2022.
- ColorMatic mineral lenses are not fully suitable for night driving in accordance with EN ISO 14889 and 8980-3:2022 or 12312-1:2022. This is due, among other things, to the typical material-related, slower brightening of mineral lenses compared to modern plastic lenses. The following restrictions apply: Photochromic mineral lenses without anti-reflective coating are not suitable for night driving from a centre thickness of approx. 4 mm (ColorMatic 1.60 grey: approx. 6 mm). Anti-reflective ColorMatic mineral lenses are no longer suitable for night-time driving from a centre thickness of approx. 6 mm (ColorMatic 1.60 grey: approx. 7 mm). Depending on the centre thickness, the lenses are therefore classified in filter category 0 or 1.
- In the case of self-tinting lenses, the classification into filter categories also depends on the degree of darkening.
- Due to the way self-tinting lenses work when darkened by the sun's UV light, the darkening process is very fast, while the lightening process is slow, especially at low temperatures. This is particularly important when changing the lens wearer from bright, sunlit areas to shaded or dark areas. The still dark lenses can lead to impaired vision in dark areas. If possible, the spectacles must be removed in these areas to improve vision or, in the case of high visual impairment, colourless replacement spectacles must be used until brightening has taken place.
- This effect does not occur when driving in a closed car (not a convertible), as the windows of a car are largely UV-impermeable, and the darkening of the lens is therefore reduced.
- The points listed for restrictions on use and foreseeable misuse are merely examples and do not claim to be exhaustive. Please refer to the contents of the chapter "Intended use".

### 3 Correct use


#### 3.1 Refraction & centring

- The basis for optimum correction is the distance refraction and the near refraction for presbyopic spectacle wearers, which is adapted to the reading distance of the spectacle wearer. If measuring spectacles are used to determine the lens, they should have a forward tilt of 0°. Due to the finite distance in the refraction room, it is advisable to carry out a distance adjustment when looking to infinity.



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- If the optician specifies the frame and centring data, Rodenstock will determine the best pre-decentration for some lenses regarding the lens geometry. Further information can be found in the Rodenstock product catalogue.
- Spectacle lenses must be centred in front of the wearer's eye in such a way that the applicable fitting requirements of the lens are met.
- The lenses must be incorporated in accordance with the specified centring specifications and the resulting spectacles must correspond to the transmitted order parameters so that the respective design layouts and calculations are optimally applied.
- With high values for lens angle and forward tilt, the centring data required for grinding in may deviate from the measured values for pupil distance/height of the spectacle wearer. For this reason, special attention must be paid to ensuring that the centring data of the finished spectacles match the wearer's vision points.
- On the lens bag, Rodenstock indicates the centring point distance  $e_z$  and the centring point height  $y_{t,e}$  for the lens plane as well as the product-dependent centring correction for prismatic lenses, which are intended to make it easier to fit the lenses correctly into the frame. The explanation of the contents and pictograms as well as further information on this can be found in the Rodenstock Tips & Technology Lenses.
- When ordering prismatic Rodenstock ophthalmic lenses (except manufacture), it is assumed that the prismatic values ordered were determined according to pupil centre centring (PMZ case). In this case, measuring spectacles/phoropter are not adjusted during the refraction. The prism effective in front of the eye results from the prismatic measuring lens and the resulting prismatic effect of the spherical/toric measuring lens. This corresponds to the resulting prism in the WinFit ordering tool.
- When determining the centring data, the optician must adjust the measured values for pupillary distance and height according to the rule of thumb (0.30 mm per 1 cm/m against the base position of the corrective prism) resulting from the centring correction for products in the Standard category as usual.
- No centring correction is required for the B.I.G. Exact and B.I.G. Norm lenses, as the back surface of these products is already shifted horizontally and vertically during the calculation of the lens so that decentration is no longer necessary when grinding in. These lenses must be centred according to the centring data  $e_z$  and  $y_{t,e}$  on the lens bag (if the frame and centring data are specified).
- For more information, please refer to the current Rodenstock product catalogue or Tips & Technology.
- Most spectacle lenses are provided with permanent markings (engravings). These serve to identify the manufacturer and, in some cases, also the lens type and are generally only recognisable when the lens is held against the light at a light/dark edge.
- In most cases, spectacle lenses are stamped. These stamps are used to clarify the reference points in the lens, to check the effect (measured effect vs. reference/order effect) and to ensure correct centring by the optician. After checking the effect and the centring, the stamp on the lens must be removed.

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- Spectacle lenses are packed in a glass bag for delivery to the optician. This is labelled with the relevant data for a medical product, such as the manufacturer's address and CE mark, as well as order-related information on order and reference values and grinding information.

### 3.2 Grinding instructions


- The grinding and processing of lenses must be carried out according to the state of the art by the respective specialised companies, such as opticians and grinding workshops. At this point, reference should be made to the relevant technical literature and to the use of suitable filter systems for the wastewater in order to avoid environmental pollution.
- When grinding, care must always be taken to avoid respirable fine dust by using wet grinding or sufficient extraction equipment. Personal protective equipment appropriate for laboratory work must also be worn when working (safety goggles, mouth/nose protection, lab coat). Highly refractive plastic materials (from index 1.60) give off an unpleasant odour during grinding, which can best be counteracted by extraction.
- Any subsequent processing of the delivered ophthalmic lens, such as tinting, mirror coating or anti-reflective coating, which goes beyond the usual edge processing, is carried out at the customer's own risk and excludes any liability on the part of Rodenstock.

### 3.3 Customised products

- All customised products, such as all products manufactured by the manufactory and glass geometry specifications outside the approved geometry range, are classified as customised products within the meaning of Regulation EU 2017/745 (MDR) due to their nature as individual productions that are not manufactured in the sense of series production. Custom-made products are manufactured according to the specifications of the regulation by the optician / ophthalmologist and the current state of science and technology and fulfil as far as possible the basic safety requirements according to Annex I MDR and the applicable standard EN ISO 14889 (*Ophthalmic optics - Spectacle lenses - Basic requirements for raw-edged finished spectacle lenses*). Deviations and, if applicable, restrictions of the authorised use are indicated by Rodenstock together with the required manufacturer documentation (see Annex XIII MDR). Any resulting risks must be weighed up by the issuer of the prescription (optician / ophthalmologist) against the benefits for the spectacle wearer and documented in the customer file.

### 3.4 Special designs

- There are a number of order parameters (such as inset reduction, base curve request, adjustments to thickness reduction prisms or prisms, etc.) that can change the performance of the lenses if necessary, in order to customise lenses to individual customer requirements. This also includes the combination of different lens types in one pair of glasses. The use of these parameters, as well as the responsibility for weighing up the risks and benefits individually for each customer, is the responsibility of the fitter/optician. The intended use and the possible degrees of freedom of the products can be found in the instructions for use of the respective products and in the Rodenstock product catalogue.


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### 3.5 Customised production or lens order according to sample

- Individual and repeat orders of lenses are generally possible. Please note that base curves, thickness reduction prism, colours and anti-reflective coatings, for example, may not match. When ordering, it is therefore advisable to state the value of the counter lens so that these can be matched to each other when calculating the base curves and thickness reduction prism.
- Compensating lenses do not fulfil the optical requirements of prescription lenses.
- White lenses with anti-reflective coating: Replacement of a single lens is possible. Depending on age, deviations in the reflective colour must be tolerated.
- Coloured plastic lenses or self-tinting mineral and plastic lenses: Production is only possible in pairs. Significant colour deviations must be accepted for individual orders.
- Customisation of ColorMatic IQ 2 Sun or ColorMatic 3 Sun lenses is generally not possible.

### 3.6 Care instructions

- Even if all spectacle lenses with premium coatings from Rodenstock are finished in such a way that they can be cleaned with a standard microfibre cloth, Rodenstock recommends cleaning the lenses under running lukewarm water with a pH-neutral cleaning agent, a diluted washing-up liquid that does not have any refatting properties or a solvent-free spectacle care product. Eyeglass lenses must not be cleaned with harsh household cleaners, liquids containing solvents, organic solvents (acetone etc.), acids or alkalis. Rodenstock recommends a clean, fine fibre microfibre or cotton cloth for drying.
- If necessary, an ultrasonic cleaning basin can be used occasionally in case of heavy soiling. To avoid possible damage to the lenses or the frame, this type of cleaning should be carried out no more than once a month and the exposure time should be limited to around 1 to 2 minutes.
- For stubborn stains on the glass, such as hairspray, the glass surface can also be carefully cleaned with a solvent-dampened cloth. The frame should not meet the solvent, as its surfaces are usually attacked by solvents.
- Glasses should never be placed on the front of the lenses.
- A sturdy glasses case is the best way to store your glasses.
- Glasses should be protected from exceptionally high temperatures, such as those that can occur in a sauna or in a parked car in the sun.
- Lenses that are provided with a temporary "anti-fog" property on the surface, must be cleaned carefully depending on the manufacturing process and, if necessary, prepared again with a special cloth or spray. It is essential to follow the manufacturer's instructions.

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### 3.7 Rodenstock trademark


- Each (right) Rodenstock branded lens is engraved with the visible Rodenstock trademark on the upper outer edge of the lens when the frame and centring data are specified. The Rodenstock brand engraving is a promise of quality. It guarantees the authenticity of your high-end precision spectacle lens from Rodenstock and offers you the security and comprehensive service of the Rodenstock brand.



Illustration 1 Visible Rodenstock trademark

## 4 Risks & side effects

- Influencing factors such as high blood pressure, diabetes, pregnancy, changes in medication, etc. can lead to the lens no longer being optimally adjusted to the wearer. In these cases, asthenopic complaints such as blurred vision, headaches, rapid fatigue and general discomfort, redness, pain and tearing in the eyes, occasionally double vision, dizziness, and a feeling of heaviness in the eyelids may occur.
- Lenses with a centre thickness minimisation may be supplied with sharp edges, there is a risk of cutting.
- With sharp-edged plus lenses or if the lens breaks during processing, there is an additional risk of cuts on sharp edges. The use of gloves helps here (but do not use them when working with rotating tools - risk of accident).
- Depending on the Abbe number of the lens material used, disturbing colour fringing may occur due to dispersion. The following applies: the higher the refractive index, the thinner the lens can be and the lighter the spectacles. At the same time, the lower the refractive index, the lower the dispersion in a prescription lens and therefore also the "colour fringing" perceived as disturbing in peripheral vision at the edge of the spectacles.
- Plastic lenses are more shatterproof than mineral lenses. However, plastic lenses can still break under unfavourable circumstances.
- Polarised lenses can lead to problems with the readability of displays such as navigation systems, screens and head-up displays and can therefore not be used without restriction, e.g. for driving.
- The materials and coatings of Rodenstock spectacle lenses have been tested for their toxic and allergenic properties and are classified as safe for proper use in accordance with EN ISO 14889. Allergy-inducing materials are not used in plastic spectacle lenses. However, allergic reactions may occur in exceptional cases in the event of special intolerances. The spectacle wearer should clarify this with their family doctor and, if in doubt, provide this information to the manufacturer.
- For spectacle wearers with intraocular lenses (IOL) who are to be fitted with B.I.G. EXACT spectacle lenses, measurements on the DNEye Scanner may or may not be successful, depending on the IOL type. The fitter can try a measurement with the DNEye Scanner but must then critically assess the course and result of each individual measurement with his or her expertise.

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## 5 Waste disposal

- Lenses should be disposed of in the residual waste.  
Intact spectacles can also be donated to charitable organisations, which then distribute them to people in need of visual aid worldwide.
- Dirty water and grinding residues produced when grinding optical glass must be disposed of properly (see instructions from the grinding machine manufacturer).

Further information on Rodenstock ophthalmic lenses can be found in the instructions for use for the respective product category.

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