

## **Instructions for use Rodenstock Manufaktur For opticians**

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## Instructions for use Rodenstock Manufaktur For opticians

**When selling medical devices, the user, 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 writing.**  
Convince your customers with your professional competence by also pointing out relevant usage restrictions during your individual and personal consultation.

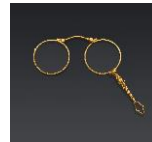
You can find important information about Rodenstock lenses at any time at <https://www.rodenstock.de/de/de/instructions-for-use.html>

### 1 Intended use

#### 1.1 Intended use & target group

Manufaktur lenses are spectacle lenses that serve to correct customer-specific refractive errors such as hyperopia (long-sightedness), myopia (short-sightedness) and/or astigmatism as well as positional errors of the eyes and age-specific presbyopia, offering individual special lens solutions, e.g. for

- Aniseikonia
- Extreme powers for the extremely short- or long-sighted spectacle wearers
- Diving or swimming goggles
- Multifocal lenses for children for the treatment of accommodative strabismus
- Multifocal lenses with individually arranged additional lenses for e.g. professional groups with special requirements in the near vision area, such as surgeons or craftsmen.
- Bilenses for lorgnettes, monocles, foreholders and pince-nez.



All Manufaktur lenses are custom-made and are individually calculated and measured in the Manufaktur calculation office.

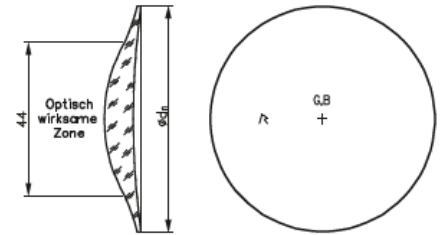


## 1.2 Manufaktur single vision lenses for high refractive errors

All Manufaktur single vision lenses are adjusted according to eye rotation point requirement.

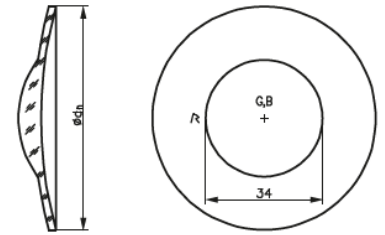
### Perfaster 1.50

- Star lenticular lens for high hyperopia in plastic
- In order to also take into account the field of view requirement for lenticular lenses the smallest possible corneal vertex distance and a low forward tilt are recommended.



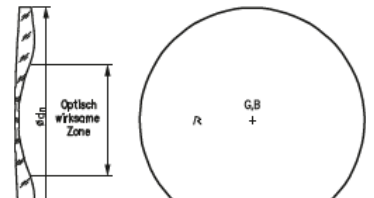
### Starlenti 1.50

- Lenticular lens for high hyperopia in plastic



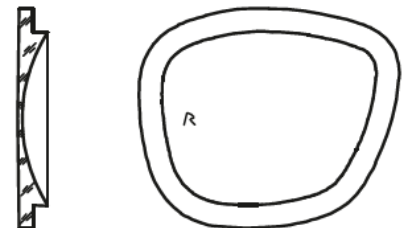
### Lentilux 1.70

- Aspherical, high refractive lenticular lens for medium to high myopia in mineral
- In order to also take into account the visual field requirement for lenticular lenses, the smallest possible corneal vertex distance and low pre-tilt are recommended.



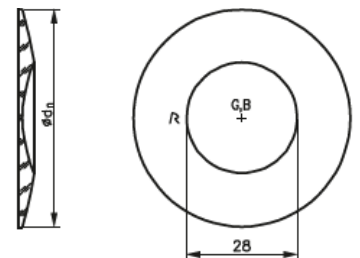
### Formlenti plan 1.50 / 1.70

- Lenticular lens for high myopia in plastic and mineral
- Plane base lens with power segment according to frame shape
- Width of the flat edge approx. 5mm



### Lenti concave 1.50 / Lenti concave 1.70

- Lenticular lens for high myopia in mineral
- Other ground lens and base lens diameters possible

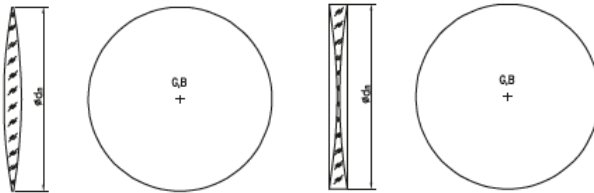


### 1.3 Manufaktur single vision lenses for special glazing

All Manufaktur single vision lenses are adjusted according to eye rotation point requirement.

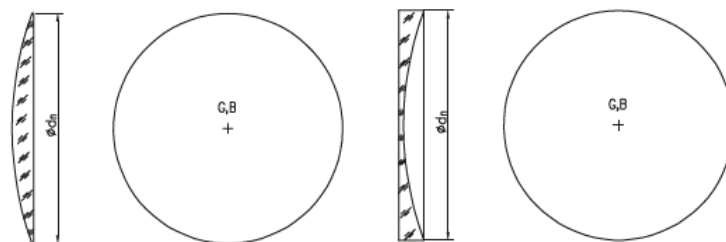
Biconvex / Biconcave 1.50

- Bilenses in mineral
- Suitable for glazing lorgnettes, pince-nez, monocles or foreholders



Plano-convex / Plano-concave 1.50 / 1.70

- Special lens for gluing into diving goggles in mineral
- Prescription lenses are applied to an existing faceplate or incorporated directly into the mask.

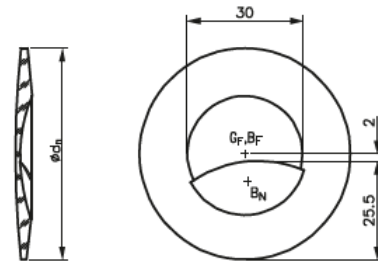


Additional information on the construction of single vision lenses can be found in the "Instructions for use Rodenstock single vision."

## 1.4 Manufaktur multifocal lenses for high refractive errors

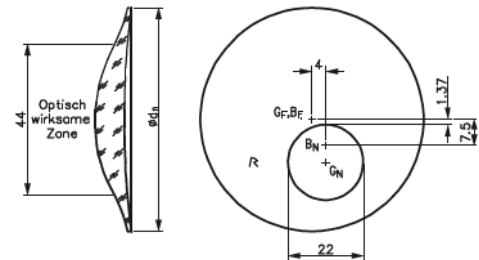
### Ardis Lenti concave 1.50

- Bifocal lenticular lens for high myopia in mineral
- Image jump free
- Usable near segment height approx. 13 mm
- Swivelling of the near segment 6° as standard, deviating or no swivel available
- Different prisms at far and near possible
- Fitting recommendation: Horizontal to far PD (BF) and vertical upper edge of near segment to lower edge of eyelid.
- Addition measurement convex side (cx)



### Perfaster Bifo 1.50

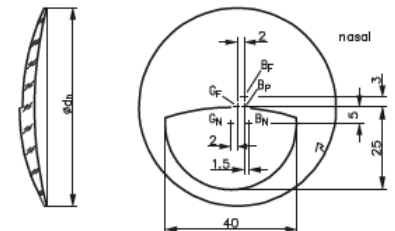
- Bifocal lens for correction of aphakia in plastic
- Near segment swivelling 18° as standard, deviating near segment swivel available
- Fitting recommendation: Horizontal to far PD (BF) and vertical upper edge of near segment to lower edge of eyelid.
- Addition measurement convex side (cx)



## 1.5 Manufaktur multifocal lenses for special glazing

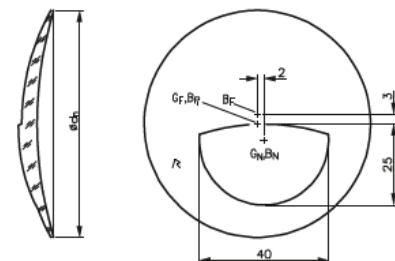
### Excelit AS 1.50 (C40)

- Bifocal lens specially developed for children for the treatment of accommodative strabismus in plastic
- Fitting: For habitual head and body posture and zero gaze direction, the lens should be fitted so that the upper edge of the near segment is at the level of the centre of the pupil. For children with accommodative strabism, the near segment height is set higher than for adults to ensure that near vision always occurs through the near segment. In aphakic children, the edge of the near segment may be lower. In the horizontal plane, Excelit AS is centred according to far PD.
- Addition measurement convex side (cx)



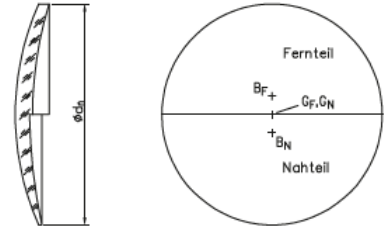
### Datalit Bifo 1.50 (C40)

- Bifocal lens in plastic with very large near field of vision
- Suitable for work on the computer or for e.g. editors, writers and craftsmen
- Adjustment: Horizontally according to far PD (BF) and vertically upper edge of the near segment to lower of eyelid. If the base lens is not used for distance, but for the intermediate distances, the horizontal centring is also done according to far PD.
- Addition measurement convex side (cx)



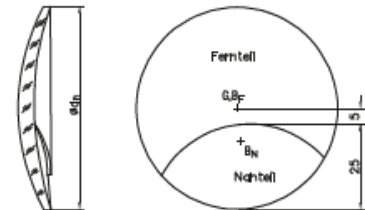
### Excellent 1.50

- Bifocal lens in mineral with very large far and near segment for e.g. editors, tradesmen, writers
- Different prisms possible in far and near segment
- Dividing line shifting possible
- Image jump free
- Also possible as trifocal lens
- Adjustment: Horizontal to far PD ( $B_F$ ) and vertical edge of near segment to lower edge of eyelid.



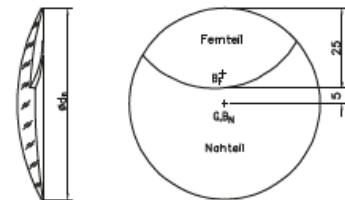
### Ardis 1.50

- Special bifocal lens in mineral with large near segment, e.g. for doctors, craftsmen
- Different prisms possible in far and near segment
- Standard swivel = 6°, deviating or no swivel available
- Image jump free
- Adjustment: Horizontal to far PD ( $B_F$ ) and vertical to upper edge of of near segment to lower edge of eyelid.



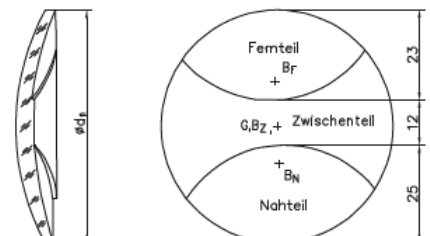
### Ardis reversed 1.50

- Special bifocal lens with small far segment at the top for overhead work and extra large near segment in mineral
- Different prisms possible in far and near segment
- Standard swivel = 6°, deviating or no swivel available
- Image jump free
- Adjustment: Horizontal to near PD ( $B_N$ ) and vertical  $B_N$  to pupil centre at zero line of sight.



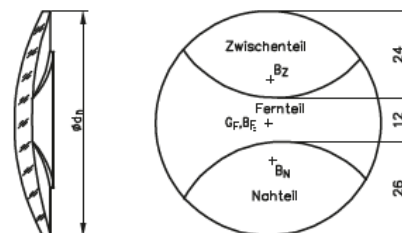
### Ardis FZN 1.50

- Special trifocal lens in mineral e.g. for doctors, pilots, craftsmen
- Configuration from top to bottom - Distance, Intermediate, Near Additional p segment freely selectable. Standard approx. 1/2 addition
- Standard swivel 6° (far segment 3° outwards/ near segment 3° inwards), deviating or no swivel available
- Different prisms possible in the power segments
- Image jump free
- Adjustment: Horizontal and vertical individually, depending on visual requirements



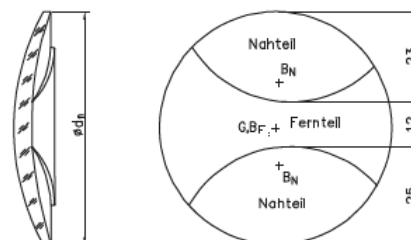
### Ardis ZFN 1.50

- Special trifocal lens in mineral e.g. for fitters, electricians
- Configuration from top to bottom - Intermediate, Distance, NearSwivel:  $\text{int} = 3^\circ$ ,  
far segment to near segment =  $6^\circ$ , deviating or no swivel available
- Different prisms possible in the power segments
- Additional power of the intermediate segment freely selectable.  
Standard approx. 1/2 addition
- Image jump free
- Adjustment: Horizontal to far PD (BF) and vertical BF to pupil centre at zero line of sight.



### Ardis NFN 1.50

- Trifocal special lens in mineral
- Configuration from top to bottom - Near, Distance, Near
- Special lens e.g. for craftsmen, fitters
- Standard swivel =  $6^\circ$ , deviating or no swivel available
- Different prisms possible in the power segments
- Image jump free
- Adjustment: Horizontal to far pd (BF) and vertical BF to pupil centre at zero line of sight.



Additional information on fitting multifocal lenses can be found in the instructions for use Rodenstock multifocal lenses.

## 1.6 Further information

- All Manufaktur lenses are calculated for the measurement position.
- Unless otherwise stated, the order values of all multifocal and single-focal lenses should be checked in the concave measuring position.
- Especially when looking through the near segment, the beam path in the as worn position deviates from the beam path in the measurement position. In the case of medium to strong powers, the spectacle wearer is thus undercorrected or overcorrected at near.

In the range of medium to strong positive powers, the addition in the as worn position is smaller than in the measurement position. In the minus range, however, the addition in the as worn position would be higher than in the measurement position.

When ordering the lenses, it is therefore important to ensure that a corresponding correction value (related to the refracted addition, depending on the lens geometry and the object distance) is taken into account for the order addition, especially in the case of higher powers. In the case of prismatic refraction data of Manufaktur lenses, it is assumed that the refraction was carried out according to the formula case and that the measuring frame was adapted according to the rule: per 1 cm/m  $\rightarrow$  0,3 mm against prism base.

- The wearing rim asphere (Perfastar 1.50, Lentilux 1.70) avoids ring scotomas, as there is a continuous change in dioptric power in the transition zone between the optical power area and the edge of the lens. The entire field of vision is available to the spectacle wearer. When using the edge areas of the spectacle lens, the visual acuity is reduced because of the wearing edge asphere.

- With Ardis lenses, a second surface is ground into the base lens on the eye side. The different surface curvatures create an offset edge. The surfaces are inclined towards each other in such a way that the prismatic deflection is the same on both sides of the separating edge. Thus, there is no image jump when changing the view from one field of vision to the other. The arrangement of the additional segments to each other as well as the addition distribution can be selected as desired. Furthermore, different prismatic power and base positions can be achieved for the respective lens areas (difference  $\leq 8$  cm/m).
- In diving goggles, the lenses usually have a flat front surface so that they can be cemented onto the back surfaces of the plano lenses. The flat front surface also has the advantage that the dioptric power does not have to be converted for use under water. The wearer can see clearly with the goggles on the outside as well as under water.
- Swimming goggles can be glazed directly. Here, the lenses are incorporated with a step facet. With plus power, the front surface is curved. So that the power under water does not deviate too much, the flattest possible front surface is chosen. Minus lenses are manufactured with a flat front surface up to a diameter of 65 mm. It can be specified for which surrounding medium the lenses are to be calculated. However, lenses for swimming goggles are mostly ordered for use above water.
- Excelit AS is a bifocal lens for the treatment of accommodative strabismus. Triggered by the eye's incentive to accommodate to near, the eyes converge far too much, "one eye squints inwards". Without correction, there is an excessive inward movement of the eyes as a result of accommodation when looking near. The AC/A quotient, i.e. the ratio of accommodative convergence movement to accommodation used, is increased. The usual treatment method is to prescribe bifocal lenses for these children so that the eyes only have to accommodate a little or not at all when looking at near distance and therefore does not converge as much. The excess convergence is reduced by the greatly reduced accommodation. Bifocal lenses with a suitable near addition of 2.00 to 3.00 D can reduce accommodation and reduce the near squint angle. The aim here is to achieve binocular near vision. The bifocal lens must have a large, high-set near segment in order to exclude near vision past the near segment. Since the nominal position of the optical centre of the distance segment coincides with BP and the dividing line of the near segment, there is a prismatic power in the distance reference point BF (3 mm above and 2 mm nasally offset from GF) which is dependent on the far segment power; if necessary, it is superimposed on a correction prism.
- Magnifying lenses can be pure reading lenses, but also multifocal lenses with increased addition in the near segment. The advantages of magnifying lenses over telescopic systems are the simplicity of use, a large field of vision and the high image brightness. They are also relatively inconspicuous and inexpensive.
- A fitting with magnifying additions is necessary if normal correction does not achieve sufficient visual acuity for reading newspapers. In addition to the magnifying power as such, the magnifying effect is mainly produced by a reduced distance "lenses-object". By approaching an object closer than the normal reading distance, a magnified retinal image is achieved. The presbyopic eye is no longer able to accommodate to these strongly approached objects. This lack of accommodation must be replaced by a correspondingly increased near power. Convergence-supporting prisms are intended to relieve the convergence system when reading at very close distances. Rule of thumb: per 1 D addition 1cm/m  $\rightarrow$  base inside per side The prism is only given from 4 D addition.
- The calculation of Manufaktur lenses assumes a fixed tilt situation and "central" centring (horizontal and vertical) to ensure the best possible performance of the lenses.
- The satisfaction guarantee for Manufaktur lenses is only valid for the described intended use and with proper application.



## 2 Restrictions of use & foreseeable misuse

- All products of the Manufaktur are to be classified as custom-made products within the meaning of Regulation EU 2017/745 (MDR) due to their nature as custom-made products, which are not manufactured in the sense of series production.
- Manufaktur lenses are produced by the optician / ophthalmologist in accordance with the specifications of the regulation and the current state of science and technology and fulfil, as far as possible, the basic safety requirements in accordance with Annex I MDR and the applicable standard EN ISO 14889 (*Ophthalmic optics - Spectacle lenses - Basic requirements for raw-edged finished spectacle lenses*).
- Restrictions in use may result due to possible restrictions in physiological compatibility.
- Deviations and possibly even restrictions of the intended use (e.g. for driving vehicles, signal light suitability, break resistance, etc.) are indicated by Rodenstock together with the required Manufaktur documentation. Risks arising from this 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.
- Due to their nature as custom-made products, no general statement can be made about the suitability of Manufaktur lenses for driving in road traffic. The decision must be made by the optician individually for each customer and can take into account the following criteria, for example: daytime visual acuity, visual field, twilight vision and glare sensitivity, position and motility of the eyes, colour vision and stereoscopic vision and the type of lens selected.
- The diameter of the central optical zone of Lentilux 1.70 becomes smaller with increasing power. It is 40 mm at up to -10.00 D and reduces by 2 mm for every 2 D increase in power. From -18.25 D to -24.00 D it is then a constant 30 mm.
- Reference is also made to the restrictions on the use of single vision lenses and multifocal lenses.
- The points mentioned for restrictions of use and foreseeable misuse are only examples and do not claim to be complete. Reference is made to the contents of the chapter "Intended use" and "Correct use".

## 3 Correct use

- For the selection of the right Manufaktur lens type and correct centring, an anatomical adjustment of the spectacle frame to the face of the spectacle wearer is mandatory. In order to maintain the full optical performance of the lens, the wearing situation must not be changed afterwards by the optician or spectacle wearer.
- For fitting recommendations, see chapter 1 for the respective product.
- Manufaktur lenses are checked for tolerance in the reference points in accordance with ISO 8980-1 before delivery to the optician.
- Single and repeat orders of Manufaktur lenses are possible. For single lens orders, it is strongly recommended to know the values of the counter lens and to include them in the order so that they can be taken into account in the calculation. The pairing of different lens types, e.g. multifocal lens and single vision lens, is a custom-made order. Please note that the base curves, colours and anti-reflective coatings, for example, are not matched.
- Further information on Manufaktur lenses, such as the correct selection of the required product depending on the requirement profile of the spectacle wearer, can be found in the current Rodenstock product catalogue.

#### **4 Risks & side effects of Manufaktur lenses**

- Reference is made to the risks & side effects of single vision lenses and multifocal lenses.
- The following restrictions on physiological compatibility may also arise due to the respective Manufaktur lens design:
  - With conventional lenticular lenses (e.g. Starlenti , Formlenti , Lenti concave), the optically effective area passes over abruptly to the wearing edge. This results in a sudden change of the dioptric power in the transition area to the wearing edge. In the case of plus lenses (Starlenti), a roving ring scotoma, also known as jack-in-the-box-phenomenon, develops at this point, which further restricts the field of vision. This impairs orientation in space.
  - The visual acuity is reduced when using the peripheral areas of a lenticular lens.
  - Manufaktur lenses with high plus power can sometimes have very small fields of vision. These make it necessary for the wearer to move their head more. As a result, stronger swim effects may be perceived at the edge of the field of vision.
  - When switching from contact lenses to lenses, it may be difficult to adjust due to the different magnification of the lens itself and the system. The retinal image of a aphakic lens wearer is larger than the retinal image with a contact lens, resulting in increased visual acuity in the centre of the lens. As the central area appears greatly enlarged, edges of the visual field recede. This can be perceived as tunnel vision and orientation difficulties are possible.
  - Initial side effects are natural and are hardly or no longer noticed over time (approx. two to three weeks).

For further information see also “Instructions for use Rodenstock general”.

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