Instructions for use

SURGmatic S201 L - 1.009.0470
SURGmatic S201 C - 1.009.1100
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1 User instructions

Dear User,

Congratulations on purchasing this KaVo quality product. By following the instructions below you will be able to work smoothly, economically and safely.

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Please direct all questions regarding the product, service and maintenance to the
KaVo Technical Service:
Toll-free: 1-888-ASK-KAVO (888-275-5286)
Email: customerservice@kavokerr.com
Please refer to the serial number of the product in all inquiries!

For repairs, please contact KaVo Repair Service.
For scheduling or if you have any questions, please contact:
KaVo Repair Service
KaVo Dental Technologies, LLC
11727 Fruehauf Drive
Charlotte, NC 28273 USA
Toll-free Direct Customer Service: 1-888-ASK-KAVO (888-275-5286)
Email: techservice@kavokerr.com
www.kavo.com

Target group

The instructions for use are intended for medical professionals, in particular dentists and office personnel.

The section on Commissioning is also intended for service technicians.

General marks and symbols

- Refer to the chapter on Safety/Warning symbol
- Important information for users and service technicians
- Action request

Sterilization parameters

1. Autoclave with pre-vacuum:
   - at least 3 minutes at 135 °C (275 °F)
   - Drying time: 16 min.
2. Autoclave using the gravity method:
   - at least 10 minutes at 135 °C (275 °F)
   - Drying time: 30 min.

Suitable for disinfection in a washer disinfector
Information on the packaging

<table>
<thead>
<tr>
<th>REF</th>
<th>Catalog number</th>
</tr>
</thead>
<tbody>
<tr>
<td>SN</td>
<td>Serial number</td>
</tr>
<tr>
<td></td>
<td>Legal Manufacturer</td>
</tr>
<tr>
<td></td>
<td>CE mark according to Medical Devices Directive EC 93/42</td>
</tr>
<tr>
<td></td>
<td>Please note the electronic instructions for use</td>
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<tr>
<td></td>
<td>Note: Please note accompanying documents</td>
</tr>
<tr>
<td></td>
<td>EAC conformity mark (Eurasian Conformity)</td>
</tr>
<tr>
<td></td>
<td>GOST R certification</td>
</tr>
<tr>
<td></td>
<td>Transportation and storage conditions (Temperature range)</td>
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<tr>
<td></td>
<td>Transportation and storage conditions (Air pressure)</td>
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<tr>
<td></td>
<td>Transportation and storage conditions (Humidity)</td>
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<td></td>
<td>Protect from moisture</td>
</tr>
<tr>
<td></td>
<td>Protect from impact</td>
</tr>
<tr>
<td></td>
<td>HIBC Code</td>
</tr>
</tbody>
</table>

Hazard levels

The warning and safety notes in this document must be observed to prevent personal injury and property damage. The warning notes are designated as shown below:

**DANGER**

In cases which – if not prevented – directly lead to death or severe injury.

**WARNING**

In cases which – if not prevented – can lead to death or severe injury.

**CAUTION**

In cases which – if not prevented – could lead to minor or moderate injury.
NOTICE

In cases which – if not prevented – can lead to property damage.
2 Safety

The instructions for use are a component of the product and must be read carefully prior to use and be accessible at all times. The device may only be used in accordance with the intended use, any other type of use is not permitted.

2.1 Infection hazard

Patients, users or third parties can be infected by contaminated medical devices.
▶ Take suitable personal protective measures.
▶ Follow the instructions for use of the components.
▶ Before initial startup and after each use, process the product and accessories appropriately.
▶ Carry out the processing as described in the instructions for use. The procedure has been validated by the manufacturer.
▶ If you deviate from this procedure, it is essential to make sure that the processing is effective.
▶ Process the product and accessories appropriately before disposal.

2.2 Technical condition

A damaged device or components can injure patients, users and third parties.
▶ Use the device and components only if there is no damage on the outside.
▶ Check to make sure that the device is working properly and is in satisfactory condition before each use.
▶ Have parts with sites of breakage or surface changes checked by the Service.
▶ If the following defects occur, stop working and have the service personnel carry out repair work:
  ▪ Malfunctions
  ▪ Damage
  ▪ Irregular running noise
  ▪ Excessive vibration
  ▪ Overheating
  ▪ Dental bur or diamond is not firmly locked in the handpiece

To ensure optimum function and to prevent property damage, please comply with the following instructions:
▶ Service the medical device with care products and systems regularly as described in the instructions for use.
▶ The device should be cleaned, serviced and stored in a dry location, according to instructions, if it is not to be used for an extended period of time.

2.3 Accessories and combination with other equipment

Use of un-authorized accessories on the device or un-authorized modifications to the device can lead to injury.
2.4 Qualification of personnel

Application of the product by users lacking appropriate medical training can injure the patient, the user or third parties.

▶ Make sure that the user has read and comprehends the instructions for use.
▶ Only employ the device if the user has the appropriate medical training.
▶ Comply with national and regional regulations.

Improper use of the device can lead to burns or injuries.
▶ Never touch the handpiece head or handpiece lid to soft tissue.
▶ After treatment, place the medical device properly in the cradle without the tool.
3 Product description

SURGmatic S201 L (Mat. no. 1.009.0470)

SURGmatic S201 C (Mat. no. 1.009.1100)

The SURGmatic (S201 L/C) handpieces are electric driven dental handpieces according to 21 CFR § 872.4200 (dental handpieces and accessories) for use by a professional trained in the field of general dental medicine. The devices are electrical driven handpieces that are reusable and ergonomically shaped, and provided with a fiber optic conductor (L version). The handpiece can be sterilized in a steam sterilizer (autoclave). Equipped with a handpiece connection according to ISO 3964, the handpieces are connected to a surgical unit via the surgical motor and thus are supplied with energy, cooling water, air for treatment and light for illumination of the operating field (L version). Surgical burs and diamonds (with straight or contra-angle handpieces) according to ISO 1797 can be attached. The handpiece is equipped with an external coolant hose for irrigation of the working area. Depending on the speed set in the surgical unit, the handpiece bur rotates at up to 40,000 rpm. According to the intended use, the handpieces contact the patient’s teeth by means of a rotating bur.

3.1 Intended use

Indications for use:

The medical device is intended for the following uses: Surgery such as setting an implant, bone augmentation, sinus lift, tooth extraction procedures, implantology, osteotomy, root canal preparation and oromaxillary and facial surgery.

⚠️ CAUTION

US Federal law restricts this device to sale by or on the order of a healthcare professional / dentist.

For dental use only.

Proper Use:

According to these regulations, this product may only be used for the described application by a properly trained user. You need to comply with the following:

- the applicable health and safety regulations
- the applicable accident prevention regulations
- these Instructions for use
In accordance with these regulations, the user is required to:

- only use equipment that is operating properly
- adhere to the specified intended use
- protect himself or herself, the patient and third parties from danger
- avoid contamination from the product

### 3.2 Technical Specifications S201 L / S201 C

**CAUTION**

It is not permissible to combine the unit with other heads / bases. Risk of injury.

- The SURGmatic S201 L/ C contra-angle handpiece consists of a base and a head and must not be combined with other heads or bases.

<table>
<thead>
<tr>
<th>Drive speed</th>
<th>max. 40,000 rpm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labeling</td>
<td>1 green ring</td>
</tr>
<tr>
<td>Speed transmission</td>
<td>20 : 1</td>
</tr>
<tr>
<td>Torque</td>
<td>max. 55 Ncm</td>
</tr>
</tbody>
</table>

With push-button chuck.

Usable with surgical burs or diamonds with internal cooling.

Internal cooling system (acc. to Kirschner and Meyer) and external cooling-medium connection.

The contra-angle handpiece can be mounted on all INTRAmatic (LUX) motors and motors fitted with a connector in accordance with ISO 3964.

### 3.3 Transportation and storage conditions

- Do not store in a refrigerated environment.

<table>
<thead>
<tr>
<th>Temperature:</th>
<th>-20 °C to +70 °C (-4 °F to +158 °F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative humidity:</td>
<td>5% RH to 95% RH absence of condensation</td>
</tr>
<tr>
<td>Air pressure:</td>
<td>700 hPa to 1060 hPa (10 psi to 15 psi)</td>
</tr>
<tr>
<td>Protect from moisture (Keep dry)</td>
<td></td>
</tr>
</tbody>
</table>
4 Startup and shut-down

**WARNING**

**Hazard from contaminated products.**
Infection hazard for dentist and patient.
▶ Prior to initial startup and after each use, process the product and accessories.

See also:
遵守ISO 17664处理步骤，第18页

**WARNING**

**Dispose of the product in the appropriate manner.**
Infection hazard.
▶ Process the product and accessories before disposal.

See also:
遵守ISO 17664处理步骤，第18页

4.1 Checking the water quantity

**CAUTION**

**Overheating of the tooth due to insufficient amount of cooling water.**
Thermal damage to the dental pulp.
▶ Set the water amount for the spray cooling to a minimum of 50 ml/min!

**CAUTION**

**Hazard from insufficient amount of spray water.**
Insufficient spray water can cause the medical device to overheat and damage the tooth.
▶ Check the spray water channels and clean the spray tube with the nozzle needle (Mat. no. 0.410.0931) according to need.

▶ Switch off spray-air and spray-water supply on the treatment device.

▶ Cool the dental bur or diamond via the external and/or internal feed, if available. The supply can take place individually or via a coupling piece.
▶ During surgical interventions, comply with the necessary precautions regarding cooling.
▶ Use physiological, sterile cooling fluid.
▶ Ensure that the coolant supply is free of air.
5 Operation

5.1 Inserting the head

**WARNING**

Detachment of the medical device during treatment.
If the head is not properly locked in place, it can become detached during treatment.
- Do not mount or remove the head while it is rotating. Before each treatment, check that the head is firmly seated and that the clamping ring is tight.

**CAUTION**

It is not permissible to combine the unit with other heads / bases.
Risk of injury.
- The SURGmatic S201 L/ C contra-angle handpiece consists of a base and a head and must not be combined with other heads or bases.

**Note**
The head of the SURGmatic S201 L / C contra-angle handpiece should be taken off the base for processing purposes only.

- Rotate the clamping ring in the direction of the arrow until it hits the stop and hold it there.
- Insert the head to the stop. Make sure that the catches engage properly.
- Rotate the clamping ring in the direction of the arrow (-> close) and tighten it.
- Attach the spray clip.
- Make sure that the spray clip is securely affixed.

5.2 Pulling off the head

- Pull the spray clip off.
- Rotate the clamping ring in the direction of the arrow until it hits the stop and hold it there.
- Removing the medical device.
- Release the clamping ring.
5.3 Attaching the contra-angle handpiece to the motor coupling

**WARNING**

Detachment of the medical device during treatment.
A medical device that is not properly locked in place can become disconnected from the motor coupling and fall off.
- Carefully pull on the medical device before each treatment to make sure that it is securely locked onto the motor coupling.

**NOTICE**

Removing and attaching the straight or contra-angle handpiece while the drive motor is rotating.
Damage to the driver.
- Never attach or remove the straight or contra-angle handpiece while the drive motor is rotating.
- Lightly spray O-rings on the motor coupling with KaVo Spray.
- Attach the medical device to the motor coupling and turn it until the guide stud audibly snaps into place.
- Pull on the medical device to make sure that it is securely affixed to the coupling.

5.4 Pulling the contra-angle handpiece off the motor coupling

- Unlock the medical device from the motor coupling by twisting it slightly and then pulling it along its axis.

5.5 Inserting the bur or diamond

**Note**

Only use carbide burs or diamonds that conform to ISO 1797-1 type 1, are made of steel or hard metal, and meet the following criteria:
- Shaft diameter: 2.334 to 2.350 mm
- Overall length: max. 45 mm
- Blade diameter: max. 10 mm

**WARNING**

Use of unauthorized burs.
Injury to the patient or damage to the medical device.
- Comply with the instructions for use and the intended use of the bur.
- Only use burs that do not deviate from the specified data.

**CAUTION**

Injury from using worn burs.
Burs could fall out during treatment and injure the patient.
- Never use burs with worn shafts.
**CAUTION**

Danger of injury from bur.
Infections or cuts.
▷ Wear gloves or finger guards.

**CAUTION**

Hazard from defective chucking system.
The bur could fall out and cause injury.
▷ Pull on the bur to make sure that the chucking system works properly and that the bur is held securely. Wear gloves or finger guards when you check, insert or remove the insert to prevent injury and infection.

▷ Insert the bur into the segment of the head drive by twisting the tool slightly, and push it to the bur stop. Activate the button if necessary.

▷ Make sure that the tool is seated securely by pulling on it.

**5.6 Removing the bur or diamond**

**WARNING**

Hazard from rotating bur.
Lacerations and damage to the chuck system.
▷ Do not touch the bur while it is rotating!
▷ Never press the push-button while the bur is rotating!
▷ Remove the bur from the contra-angle handpiece after treatment to avoid injury and infection when putting it away.

▷ After the bur or diamond has stopped rotating, firmly press the button with your thumb and simultaneously pull out the bur or diamond.
6 Checking for malfunctions and troubleshooting

6.1 Check for malfunctions

⚠️ **CAUTION**

Product heats up.
Burn injury or product damage due to over-heating.
- Do not continue working if the product heats up irregularly.

- The medical device overheats while working:
  Service the medical device.
- When the speed drops or is uneven:
  Service the medical device.
- Missing O-ring on the motor coupling:
  Replace O-ring.

See also:
- Instructions for use of motor

6.2 Troubleshooting

6.2.1 Cleaning the spray clip and the spray tube

⚠️ **CAUTION**

Hazard from insufficient amount of spray water.
Insufficient spray water can cause the medical device to overheat and damage the tooth.
- Check spray water channels and if necessary clean spray tubes with the nozzle needle (**Mat. no. 0.410.0931**).
▶ Use the nozzle pin (Mat. no. 0.410.0931) to free the water passage on the spray clip on both sides.
7 Processing steps in accordance with ISO 17664

7.1 Preparations at the site of use

**WARNING**

Hazard from contaminated products.
Contaminated products are associated with an infection risk.
▷ Take suitable personal protective measures.

**WARNING**

Sharp tool in the medical device.
Injury hazard from sharp and/or pointed tool.
▷ Remove the tool.
▷ Process the medical device as soon as possible after treatment.
▷ To minimize the risk of infection during processing, always wear protective gloves.
▷ Remove the tool from the medical device.
▷ Remove all residual cement, composite or blood immediately.
▷ Do not immerse in solutions or the like.

7.2 Non-fixing preliminary cleaning of the spray clip and spray tube

The non-fixing preliminary cleaning is a central constituent and must be performed prior to the automated processing.

Accessories required:
- Demineralized water 30 °C ± 2 °C (86 °F ± 3.6 °F)
- Nozzle needle
- Brush, e.g. medium-hard toothbrush
- Disposable syringe

**Note**
Before cleaning, take the hose off the spray clip and the contra-angle hand-piece.

▷ Check the patency of the spray clip and spray tube and clean them with the nozzle pin (Mat. no. 0.410.0931).

▷ Rinse the spray clip and spray tube with at least 20 ml demineralized water using a disposable syringe.
▷ If the spray clip and spray tube are not patent after the manual rinsing procedure, the medical device and/or the spray clip must be replaced.

▷ Brush the spray clip and spray tube under running tap water water for at least 20 seconds using a medium-hard toothbrush.
For validated internal cleaning of the spray clip and spray tube in the cleaning and disinfecting device, preliminary non-fixing cleaning is required.

### 7.3 Manual processing

#### WARNING

**Sharp tool in the medical device.**
Injury hazard from sharp and/or pointed tool.
- Remove the tool.

#### NOTICE

**Never process this medical device in an ultrasonic device.**
Functional damage and property damage.
- Clean it in a washer disinfector only.

#### Note

The spray clip for internal cooling may be additionally cleaned in the ultrasonic cleaner.

#### 7.3.1 Manual internal and external cleaning and internal and external disinfection

Not applicable.

#### 7.3.2 Manual drying

- Clean the outside and inside with compressed air until no drops of water are visible.
- Immediately after drying, lubricate the KaVo medical device with care agents from the KaVo care system.

**See also:**

2 7.5 Care products and systems - Servicing, Page 20

### 7.4 Automated processing

#### WARNING

**Incomplete disinfection.**
Infection hazard.
- Only use disinfection procedures that are verified to be bactericidal, fungicidal and virucidal.
- If the disinfectants used do not meet these requirements, the process must be concluded by disinfection of the unit(s) without packaging using a sterilizer.

#### WARNING

**Sharp tool in the medical device.**
Injury hazard from sharp and/or pointed tool.
- Remove the tool.
7.4.1 Automated internal and external cleaning and internal and external disinfection

Note
Prior to cleaning or disinfection in a washer disinfector, attach the head to an appropriate base.

KaVo recommends washer disinfectors in accordance with ISO 15883-1, which are operated using alkaline cleaning agents.

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the washer disinfector.
- For the spray clip and spray tube, also use the adapter for external spray channels.

7.4.2 Automated drying

The drying procedure is usually part of the cleaning program of the washer disinfector.

Note
Please comply with the instructions for use of the washer disinfector.

- In order to prevent impairment of the KaVo medical device, make sure that the inside and outside of the device is dry after the end of the cycle.
- Immediately after drying, lubricate the KaVo medical device with care agents from the KaVo care system.

7.5 Care products and systems - Servicing

WARNING
Sharp tool in the medical device.
Injury hazard from sharp and/or pointed tool.
- Remove the tool.
CAUTION

Improper service and care.
Risk of injury.
▶ Perform regular proper care and servicing.

Note
KaVo only guarantees that its products will function properly if the care products listed as accessories are used, since these products have been tested for proper use on our products.

7.5.1 Servicing with KaVo Spray

Note
Head can be serviced alone or attached to a shank.

KaVo recommends servicing the product after each time it is used, i.e. after each automated cleaning and before each sterilization.
▶ Remove the tool from the medical device.

▶ Cover the medical device with the KaVo Cleanpac bag, and place it on the corresponding care adapter.

▶ Press the spray key once for 1-2 seconds.

Servicing the chucking system

KaVo recommends cleaning and servicing the chuck system once a week.
▶ Remove the tool from the medical device.

▶ Position the tip of the spray nipple in the opening, and apply the spray.

▶ Press the spray key once for 1-2 seconds.

7.5.2 Servicing with KaVo QUATTROcare PLUS

Note
Head can be serviced alone or attached to a shank.

Servicing and cleaning device with expansion pressure for internal cleaning of inorganic residues and optimum servicing.
KaVo recommends servicing the product as part of the processing after each use, i.e. after each cleaning, disinfection, and before each sterilization.
▶ Remove the tool from the medical device.

▶ Service the product in the QUATTROcare PLUS.

See also:
Instructions for use KaVo QUATTROcare PLUS
Servicing the chuck

KaVo recommends servicing the chuck system once a week using the chuck servicing program integrated in the device.

**Note**
Handpieces must be taken off the service couplings before the chuck service can be started and run.

- Close the front door and press the chuck service button for at least three seconds until the spray canister control LED flashes three times consecutively.
  - The device is in chuck service mode.
- Remove the service coupling chuck from the side hatch of the QUATTROcare PLUS and attach it to coupling service station four, on the far right. A MULTIflex adapter must be mounted there.
- Press the handpiece together with the guide bush of the chuck to be serviced against the tip of the service coupling.
- Press the button marked with the chuck service symbol.

**Note**
**Close the chuck service mode.**
Option 1: Place the dental handpieces in the QUATTROcare PLUS 2124 A, close the front door and start the service procedure.
Option 2: After three minutes with no service procedure running, the device automatically switches back to normal service mode.

See also:
Servicing with KaVo QUATTROcare PLUS

7.6 Packaging

**Note**
The sterile goods package must be large enough for the product so that the packaging is not stretched.
The quality and use of the sterilization packaging must comply with applicable standards and be suitable for the sterilization procedure!
- Seal each medical device individually in a sterilization item package.

7.7 Sterilization

Sterilization in a steam sterilizer (autoclave) in accordance with ISO 17665-1

⚠️ **CAUTION**
**Improper service and care.**
Risk of injury.
- Perform regular proper care and servicing.
NOTICE

Contact corrosion due to moisture.
Damage to the product.
▪ Remove the product from the steam sterilization immediately after the sterilization cycle.

The KaVo medical device has a maximum temperature resistance of up to 138 °C (280.4 °F).

Sterilization parameters:
Select a suitable process (depending on the device) from the following sterilization processes.

Sterilizer with triple pre-vacuum:
▪ at least 3 minutes at 135°C (275 °F)
  Drying time: 16 min.

Sterilizer using the gravity method:
▪ at least 10 minutes at 135°C (275 °F)
  Drying time: 30 min.
▪ Remove contra-angle handpieces and turbines immediately after the completion of the sterilization cycle from the sterilizer.
▪ Use in accordance with the manufacturer's Instructions for Use.

7.8 Storage
Processed products must be stored, protected from bacteria, to the extent possible, and dust, in a dry, dark, cool room.

Note
Comply with the expiration date of the sterilized items.
8 Tools and consumables

Available from dental suppliers.

<table>
<thead>
<tr>
<th>Material summary</th>
<th>Mat. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spray head INTRA (KaVo Spray)</td>
<td>0.411.9911</td>
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<tr>
<td>Service coupling for heads (QUATTROcare)</td>
<td>0.411.7941</td>
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<tr>
<td>Spray clip</td>
<td>1.002.3377</td>
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<td>Coupling piece</td>
<td>0.593.0361</td>
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<td>Nozzle needle</td>
<td>0.410.0931</td>
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<tr>
<td>Instrument stand 2151</td>
<td>0.411.9501</td>
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<td>Cleanpac 10 units</td>
<td>0.411.9691</td>
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<td>Cellulose pad 100 units</td>
<td>0.411.9862</td>
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<td>Surgery service coupling</td>
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<th>Material summary</th>
<th>Mat. No.</th>
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<tbody>
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<td>KaVo Spray USA and Canada 2113 A</td>
<td>0.411.9660</td>
</tr>
<tr>
<td>QUATTROcare plus Spray USA and Canada 2141 P</td>
<td>1.005.4524</td>
</tr>
<tr>
<td>Chuck care set</td>
<td>1.003.1253</td>
</tr>
</tbody>
</table>
9 Terms and conditions of warranty

The following Terms and conditions of warranty apply to this KaVo medical device:

KaVo provides the end customer with a warranty of proper function and guarantees zero defects in respect of material and processing for a period of 24 months from the date of the invoice, subject to the following conditions:

In case of justified complaints, KaVo will honor its warranty with a free repair or replacement, as needed. Other claims of any nature whatsoever, in particular with respect to compensation, are excluded. In the event of default, gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.

KaVo shall not be liable for defects and their consequences that have arisen or may arise from natural wear, improper handling, cleaning or maintenance, non-compliance with operating, maintenance or connection instructions, calcination or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with KaVo's instructions for use or other manufacturer's instructions. The warranty granted does not usually extend to lamps, optical fibers made of glass and glass fibers, glassware, rubber parts, and the colorfastness of plastic parts.

All liability shall be excluded if defects or their consequences originate from manipulations or changes to the product made by the customer or a third party that is not authorized by KaVo.

Warranty claims shall be accepted only if the product is submitted along with proof of purchase in the form of a copy of the invoice or note of delivery. The dealer, purchase date, type, and serial number must be clearly evident from this document.