Instructions for use

SURGmatic S11 L - 1.009.1010
SURGmatic S11 C - 1.009.1005
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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: techservice@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

| ![Warning] | Refer to the chapter on Safety/Warning symbol |
| ![Information] | Important information for users and service technicians |
| ![Action] | Action request |

### Sterilisation parameters

1. Steriliser with triple pre-vacuum:
   - at least 3 minutes at 135°C (275 °F)
   - Drying time: 20 min.
2. Steriliser using the gravity method:
   - at least 10 minutes at 135°C (275 °F)
   - Drying time: 30 min.
3. Steriliser using the gravity method:
   - at least 60 minutes at 121°C (250 °F)
   - Drying time: 30 min.
Information on the packaging

<table>
<thead>
<tr>
<th>REF</th>
<th>Material number</th>
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<tbody>
<tr>
<td>SN</td>
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<tr>
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<td>CE mark according to Medical Devices Directive EC 93/42</td>
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<td></td>
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<td>EAC conformity mark (Eurasian Conformity)</td>
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<td></td>
<td>GOST R certification</td>
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<td></td>
<td>Transportation and storage conditions (Temperature range)</td>
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<td>Transportation and storage conditions (Air pressure)</td>
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Hazard levels

The warning and safety notes in this document must be observed to prevent personal injury and material 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 – could lead to death or severe injury.
1 User instructions

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

NOTICE
In cases which – if not prevented – could lead to material 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 could 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, reprocess the product and accessories appropriately.
▶ Carry out the reprocessing 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 reprocessing is effective.
▶ Reprocess the product and accessories appropriately before disposal.

2.2 Technical condition

A damaged device or components could injure patients, users and third parties.

▶ Only operate devices or components if they are undamaged on the outside.
▶ Check 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 diamonds is not firmly locked in the handpiece

Observe the following instructions in order to guarantee optimum functioning and prevent material damage:

▶ 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 will not be used for a longer period.

2.3 Accessories and combination with other equipment

Use of un-authorised accessories or un-authorised modifications of the device could lead to injury.
2 Safety | 2.4 Qualification of personnel

▶ Only use accessories that have been approved for combination with the product by the manufacturer.
▶ Do not make any modifications to the device unless these have been approved by the manufacturer of the product.
▶ Use original KaVo spare parts only.

The lack of control equipment for changing the speed range and the direction of rotation can lead to injury.
▶ Control facility for changing the speed and the direction of rotation must be present.
▶ The medical device may only be combined with a treatment centre released by KaVo.
▶ Comply with the Instructions for Use of the treatment centre.

2.4 Qualification of personnel

Application of the product by users without the appropriate medical training could injure the patients, the users or third parties.
▶ Make sure that the user has read and understood the instructions for use.
▶ Only employ the device if the user has the appropriate medical training.
▶ Observe national and regional regulations.

The improper use of the device could lead to burns or injuries.
▶ Never touch soft tissue with the handpiece head or instrument cover.
▶ After treatment, place the medical device properly in the cradle without the tool.
3 Product description

SURGmatic S11 L (Mat. no. 1.009.1010)

SURGmatic S11 C (Mat. no. 1.009.1005)

3.1 Purpose – Proper use

Indications for use:
This medical device is

- intended for dental treatment only. All other types of use or alterations to the product are not permitted and can be hazardous. The medical product is designed to be used with the corresponding heads in the following applications: surgery e.g. placing an implant, bone augmentation, sinus lift, dental extraction, implantology and maxillo-facial surgery.
- A medical device according to relevant national statutory regulations.

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

According to these regulations, the user is required to:

- to only use equipment that is operating correctly
- adhere to the specified intended use
- to protect him or herself, the patient and third parties from hazards
- to prevent contamination from the product

3.2 Technical Specification

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
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<tr>
<td>Drive speed</td>
<td>max. 40,000 rpm</td>
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<tr>
<td>Identification</td>
<td>1 blue ring</td>
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<tr>
<td>Speed transmission</td>
<td>1:1</td>
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<tr>
<td>Maximum speed:</td>
<td>max. 40,000 rpm</td>
</tr>
</tbody>
</table>

Handpiece cutters or grinders can be used.
The handpiece can be mounted on all INTRAmatic (LUX) motors, and motors with a connection in accordance with EN ISO 3964.

3.3 Transportation and storage conditions

- Do not store in a refrigerated environment.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>-20°C to +70°C (-4°F to +158°F)</td>
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<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</td>
<td></td>
</tr>
</tbody>
</table>

Protect from moisture
4 Start up and shut down

⚠️ WARNING
Hazard from non-sterile products.
Infection hazard for dentist and patient.
▶ Before first startup and after each use, reprocess and sterilise the medical device and accessories accordingly.

⚠️ WARNING
Dispose of the product in appropriate manner.
Infection hazard.
▶ Before disposal, reprocess and sterilise the product and accessories appropriately.

4.1 Checking the amount of water

⚠️ CAUTION
Overheating of the tooth due to insufficient amount of cooling water.
Thermal damage to the dental pulp.
▶ Adjust 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.
▶ Cooling the drill bit or bur via external supply.
▶ During surgical interventions, comply with the necessary precautions regarding cooling.
▶ Use physiological, sterile cooling fluid.
5 Operation

5.1 Attach the medical device

**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 ensure that it is securely locked onto the motor coupling.

**CAUTION**

Connect to the drive motor.
Handpiece blocked.
- Only start the handpiece when the chuck is closed.

**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 motor coupling with KaVo Spray.
- Place the medical device on the motor clutch and lock it into place. With the SURGmatic S11 L, the latch must lock into place audibly.
- Pull on the medical device to make sure that it is securely affixed to the coupling.

5.2 Remove the medical device

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

5.3 Insert the handpiece or contra-angle handpiece drill bit.

**Note**

Only use handpiece or contra-angle handpiece burs that correspond to EN ISO 1797 type 1 and type 2, are made of steel or hard metal and meet the following criteria:
- Shaft diameter: Ø 2.334 to Ø 2.350 mm
- Contra-angle burs with bur stop:
  - Shaft clamping length: at least 12 mm
  - Overall length: max. 22 mm
- Handpiece burs without bur stop:
  - Shaft clamping length: at least 30 mm
  - Overall length: max. 44.5 mm
5 Operation

5.4 Remove the handpiece or contra-angle drill bit

⚠️ WARNING

Use of unauthorised cutters or grinders.
Injury to the patient or damage to the medical device.
▷ Observe the instructions for use and use the cutter or grinder properly.
▷ Only use cutters or grinders that do not deviate from the specified data.

⚠️ CAUTION

Use of dental burs or diamond grinders with worn or damaged shafts.
Risk of injury, tool may fall out during treatment.
▷ Never use dental burs or diamond grinders with damaged or worn shafts.

⚠️ CAUTION

Danger of injury from cutters or grinders.
Infections or cuts.
▷ Wear gloves or finger stalls.

⚠️ CAUTION

Hazard from defective chuck system.
The cutter or grinder could fall out and cause injury.
▷ Pull on the dental burr or rips abrasives to check if the clamping system is functioning properly and that the tool is firmly clamped. Wear gloves or a thimble to check, insert, or remove the bits to prevent injury and infection.

▷ Rotate the clamping ring in the direction of the arrow to the backstop and insert the handpiece cutter or polisher into the chuck.

▷ Turn the clamping ring back into its initial position.

▷ Check that the cutter or grinder is securely attached by pulling on it.

5.4 Remove the handpiece or contra-angle drill bit

⚠️ WARNING

Hazard from rotating cutter or grinder.
Lacerations and damage to the chucking system.
▷ Do not touch the cutter or grinder when it is rotating!

▷ Remove the cutter/grinder from the contra-angle handpiece after treatment to avoid injury and infection when putting it away.

▷ After the milling or grinding tool has come to a standstill, turn the clamping ring as far as it will go and remove the milling or grinding tool.

▷ Turn the clamping ring back into its initial position.

5.5 Conversion for contra-angle handpiece drill bit

Note
The handpiece must be converted to use contra-angle handpiece drill bits.

▷ Open the handpiece chuck.

▷ Insert the enclosed bur stop in the chuck.

▷ Press contra-angle bur to bur stop, close clamping ring and check that it is firmly seated.

▷ Use the enclosed hook to remove the bur stop.
6 Troubleshooting

6.1 Check for malfunctions

⚠️ CAUTION

Heating of the product.
Burns or product damage from overheating.
▶ Do not use the product if it is irregularly heated.

▶ The medical device is too hot while working:
Service the medical device.

▶ When the speed drops or is uneven:
Service the medical device.

▶ An O-ring is missing on the motor coupling:
Replace O-ring.

See also:
Instructions for use of motor

6.2 Troubleshooting

6.2.1 Cleaning 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 needle (Mat. no. 0.410.0931) to free the water passage at the spray tubes.
7 Reprocessing steps in accordance with EN ISO 17664

7.1 Preparation at the site of use

⚠️ **WARNING**
**Hazard from contaminated products.**
Contaminated products are associated with an infection hazard.
- Take suitable personal protective measures.

⚠️ **WARNING**
**Sharp tool in the medical device.**
Injury hazard from sharp and/or pointed tool.
- Remove the tool.
- Remove the tool from the medical device.
- Remove all residual cement, composite or blood immediately.
- Reprocess the medical device as soon as possible after treatment.
- The medical device must be dry when transported to reprocessing.
- Do not place in solutions or similar substances.

7.2 Non-fixing preliminary cleaning of the spray tube

Accessories required:
- Demineralised water 30 °C ± 2 °C (86 °F ± 3.6 °F)
- Nozzle pin
- Brush, e.g. medium-hard toothbrush
- Disposable syringe
- Check the patency of the spray tube and clean it using the nozzle needle (**Mat. no. 0.410.0931**).
- Rinse the spray tube with at least 20 ml demineralised water using a disposable syringe.
- If the spray tube is not patent after the manual rinsing procedure, the medical device must be replaced.

Brush the spray tube and hose under running tap water for at least 20 seconds using a medium-hard toothbrush.
The non-fixing preliminary cleaning is a central constituent and must be carried out prior to the automatic reprocessing.

In the cleaning and disinfecting device, validated internal cleaning of the spray tube necessitates preliminary non-fixing cleaning.
7.3 Manual reprocessing

**WARNING**

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

**NOTICE**

**Never reprocess this medical device in an ultrasonic device.**
Malfunction and material damage.
- Clean it in a washer disinfector only.

7.3.1 Manual internal and external cleaning and internal and external disinfection

Not applicable.

7.3.2 Manual drying

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

7.4 Automated reprocessing

**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 steam steriliser.

**WARNING**

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

**NOTICE**

**Never disinfect the handpiece with chloride-containing products.**
Malfunction and material damage.
- Only disinfect in the washer disinfector.

**NOTICE**

**Never reprocess this medical device in an ultrasonic device.**
Malfunction and material damage.
- Clean it in a washer disinfector only.

In the cleaning and disinfecting device, validated internal cleaning of the spray tube necessitates preliminary non-fixing cleaning.
7.4.1 Automated internal and external cleaning and internal and external disinfection

**Note**
Prior to cleaning or disinfection in a thermodisinfector, attach the head to an appropriate shank.

KaVo recommends washer disinfectors according to ISO 15883-1, which are operated using alkaline cleaning agents.

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

7.4.2 Automated drying

The drying procedure is normally part of the cleaning programme 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 dental bur or diamond grinder in the medical device.
Risk of injury from sharp and/or pointed dental bur or diamond grinder.
- Remove dental bur or diamond grinder.

**CAUTION**

Premature wear and malfunctions from improper servicing and care.
Reduced product life.
- Perform proper care regularly!

**Note**
KaVo guarantees the proper function of KaVo products only if the care products listed as accessories are used, since these were tested for proper use on our products.

7.5.1 Care with KaVo Spray

KaVo recommends servicing the product after each use, i.e. after each automatic cleaning and before each sterilisation.

- Remove the dental bur or diamond grinder.
- Cover the product with the Cleanpac bag.
Plugging the product onto the cannula, and press the spray button for one second.

**Servicing of the clamping chuck**

KaVo recommends cleaning and servicing the chuck system once a week.

- Remove the cutter or grinder, place the spray nipple tip in the opening and spray.

**Note**

Carry out servicing according to instructions in the section "Care with KaVo Spray".

### 7.5.2 Servicing with KaVo QUATTROcare PLUS

Cleaning and servicing device with expansion pressure for internal cleaning of inorganic residues and optimum care. KaVo recommends servicing the product as part of the reprocessing after each use, i.e., after each cleaning, disinfection, and before each sterilisation.

- Remove the tool from the medical device.

- Service the product in the QUATTROcare PLUS.

**See also:**

- Instructions for use KaVo QUATTROcare PLUS

**Servicing the clamping 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 performed.

- 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 of the chuck from the side hatch of the QUATTROcare PLUS and attach it to coupling service point four, on the far right. A MULTIflex adaptor 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

7.5.3 Servicing with KaVo QUATTROcare

Note
QUATTROcare 2104 / 2104 A is no longer included in the current delivery programme.
Follow-up product:
▸ QUATTROcare PLUS 2124 A

Servicing and cleaning device with expansion pressure for the interior cleaning of inorganic residues and optimum care.
(no validated cleaning of the interior according to German Robert Koch Institute (RKI) requirements)
KaVo recommends servicing the product as part of the reprocessing after each use, i.e. after each cleaning, disinfection, and before each sterilisation.
▸ Remove the tool from the medical device.
▸ Service the product in the QUATTROcare.

Care of chucking system

KaVo recommends cleaning and servicing the chuck system once a week.
▸ Remove the tool from the medical device.
▸ Plug the spray nipple of the chuck servicing set onto the QUATTROcare plus Spray.
▸ Position the tip of the spray nipple in the opening, and apply the spray.
▸ Press the spray key for 1 to 2 seconds.

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 packaging of the items to be sterilised must satisfy the applicable standards and be appropriate for the sterilisation process!
▸ The medical device must be packed before sterilisation.
7.7 Sterilisation

Sterilisation in a steam steriliser (autoclave) in accordance with ISO 17665-1

⚠️ CAUTION
Premature wear and malfunctions from improper servicing and care.
Reduced product life.
▶ Before each sterilisation cycle, service the medical device with KaVo care products.

⚠️ CAUTION
Contact corrosion due to moisture.
Damage to product.
▶ Immediately remove the product from the steam steriliser after the sterilisation cycle!

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

Select a suitable procedure (depending on the available autoclave) from the following sterilisation processes:
- Steriliser with triple pre-vacuum:
  - at least 3 minutes at 135 °C (275 °F)
  - Drying time: 16 min.
- Steriliser using the gravity method:
  - at least 10 minutes at 135°C (275 °F)
  - Drying time: 30 min.
▶ Use according to the manufacturer's Instructions for Use.

7.8 Storage

Prepared products must be stored appropriately in a dry, dark, cool room such that they are protected from germs (as far as possible) and dust.
▶ Comply with the expiry date of the sterilised items.
### 8 Tools

Available from dental suppliers.

<table>
<thead>
<tr>
<th>Material summary</th>
<th>Mat.No.</th>
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<td>Instrument stand</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>Bur stop</td>
<td>0.524.0892</td>
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<td>Hook</td>
<td>0.410.1963</td>
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<tr>
<td>Nozzle pin</td>
<td>0.410.0931</td>
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<tr>
<td>Coupling piece</td>
<td>0.593.0361</td>
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<td>Spray head INTRA (KaVo Spray)</td>
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<td>Service coupling for heads (QUATTRO-care)</td>
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<td>Surgery service coupling</td>
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#### Only for the USA

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<td>KaVo Spray USA and Canada 2113 A</td>
<td>0.411.9660</td>
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<td>QUATTROcare plus Spray USA and Canada 2141 P</td>
<td>1.005.4524</td>
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<tr>
<td>Chuck servicing set</td>
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#### Canada only

<table>
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<tr>
<td>QUATTROcare plus Spray Canada 2149 P</td>
<td>1.005.4523</td>
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9 Terms and conditions of warranty

The following warranty conditions 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 honour its warranty with a free replacement or repair. Other claims of any kind 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 fibres made of glass and glass fibres, glassware, rubber parts, and the colourfastness of plastic parts.

All liability is 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 authorised by KaVo.

Warranty claims will only be accepted 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.