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Certified according DIN EN ISO 13485:2003
Manufactured according MPG, directive 93/42 EWG and Quality System Regulation 21 CFR 820.

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Warnings and Safety Notes

The medical product should be used as to the regulations fo the MPG, the common state of the art, and as to the prevailing labour protection and accident prevention rules.

**Note** Before using the instrument, check the product for function safety and proper state.

**Warning** Do not use the product if you have detected damages that could jeopardize the patient, the user or third persons.

**Warning** This instrument was not disinfected or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions in chapter 5 Cleaning, Disinfecting and Sterilizing, of this manual

The intubation endoscope is a high-value fine-mechanical instrument. Make sure to treat it with care.

**Warning** Avoid direct sunlight, X-rays, sudden strong temperature variations, heating above 60°C and mechanical stress such as shocks and sharp bending of the insertion tube.

**Note** Keep the ambient temperature with the permissible range.

**Warning** Be careful with pointed or sharp objects such as scalpels or needles when handling them next to the intubation endoscope.

**Warning** Using a high-performance light source and handling the fiber-optic guide or endoscope improperly, the high light intensity might cause burns. The fiber-optic exit at full light intensity must not be put directly onto the body.

**Warning** Make sure the user of the medical product has acquired the appropriate knowledge and practical experience thus granting proper handling of the product.

**Note** Operation safety and serviceability of the medical product do not only depend on the users’s competence but also on the maintenance and servicing of the medical product. Regular cleaning is mandatory (chapter 5 Cleaning, Disinfecting and Sterilizing)

**Warning** Only special personnel authorized by ACUTRONIC Medical Systems AG is allowed to do repair work.

This qualified service and the explicit use of original spare parts grant the applicability and the value of your medical product.
1. Introduction

1.1 Intended use
The intubation endoscope is a high-end medical product. It is designed to perform oral and nasal intubation.

1.2 Directions for the use of the Manual

1.2.1 Contents
The operation manual provides information about the safe, proper and efficient use of the medical device.

We recommend that you take the time to read the operation manual carefully prior to taking the medical device into operation. Preferably, start with chapter Warnings and Safety Notes. Make sure that the operation manual is within reach.

The contents of this operation manual do not, however, replace any medical or technical knowledge. Such expertise is subject to the user’s special education or further education.

ACUTRONIC Medical Systems AG is not reliable for diagnoses and interpretations of finding based on the application of this medical device. Acquiring special medical knowledge as well as drawing diagnostic and therapeutic conclusions is solely subject to the user of this medical device.

1.2.2 Text
Emphasis as listed below is used in the text for better overview and easier reading:

**bold** Monitor output

*italic* Terms

CAPITALS Labels on the equipment

underline Example

**Warning** Points out situations that may jeopardize the operation safety or human life, or destroy equipment if you do not act as stated.

**Note** Recommends actions to improve situations and enhance the operation safety. If you do not act as stated, however, the safety is not jeopardized nor does this lead to any malfunction or destruction.
2 Description

The new ACUTRONIC intubation endoscopes produce large and bright images at high resolution due to the high-capacity fiber-optic bundles and optical systems used for the lenses and eyepiece.

They have an ergonomic design. The control lever of the bending section and the fiber-optic light-guide connector have been thoughtfully designed and positioned. Even the daily routine handling remains comfortable and non-tiring.

Bending the distal tip at small radii is granted by the sensitive yet robust control.

Sophisticated high-capacity materials have been used in a functional design. The increasing stress of modern reprocessing procedures is thus be well resisted.

ACUTRONIC intubation endoscopes are:

- Gas sterilizable
- Fully immersible in disinfectant solution
- Compatible to machine reprocessing
- STERIS® compatible
3 Design

The intubation endoscopes are built of the insertion tube with its bendable distal tip, the handle, the eye piece and the focus ring. The handle incorporates the control lever to bend the distal tip and the connectors for the leakage tester and the fibre-optic light-guide cable.
4 Using

4.1 Connecting Light Source

The connector for the fibre-optic light-guide cable is equipped with an adapter of the type ACM by default. Further adapters of the types STORZ/OLYMPUS and WOLF are included in the scope of delivery.

**Warning**  
Make sure to avoid the contamination of the endoscope’s light-output end. Otherwise, the risk may arise that the distal end heats up above 41°C which is dangerous for the patient.

4.2 Connecting the CCD Camera

The DIN eyepiece allows you to connect all common endoscopic cameras to the intubation endoscope.

**Warning**  
The endoscopic cameras should comply with the standard DIN EN 60601!

Connecting the camera, bring the dioptic adjustment in its normal position as marked. Focussing is done with the camera lenses.

Matching marks: normal position of dioptic adjustments

There might occur Moiré effects in the monitor image as a result of the interference of the fibre-optic bundle pattern with the structure of the image sensor. Mostly, these effects can be considerably diminished by slightly turning the camera lenses and/or slightly defocusing at the eyepiece.
4.3 Leakage Test

Make sure to carry out the leakage test prior to each immersion such as cleaning and disinfection as well as prior to each sterilization.

**Warning** The connection hose of the leakage tester and the tester connection should be dry.

First, put the tester connection cap firmly on the tester connector and turn it clockwise one quarter turn. The tester is now firmly connected to the instrument and cannot be withdrawn.

ACUTRONIC Medical Systems AG offer the optional *adapter for leakage testers, type OLYMPUS/ACUTRONIC* to connect ACUTRONIC intubation endoscopes to the leakage testers belonging to the cleaning and disinfection machine (chapter 6.3.2 Accessories Recommended).

Next, create the maximum permissible test pressure of 160 mmHg at the leakage tester by pumping. The rubber bushing at the distal bending section of the instrument will be slightly inflated.

If the pressure does not drop, the instrument is allowed to be used or reprocessed.
Warning  If the pressure, however, drops by more than 10 mmHg within one minute (see manometer display), the instrument must not be used nor immersed in any liquid.

If this is the case, make sure to

- wipe the outer casing of the instrument using an instrument disinfectant or isopropyl alcohol 70%
- dry the channels with air pressure
- envelope the endoscope in a protective membrane
- put it in its original package and
- mark it “unthight, not disinfected”

Then, submit the endoscope to the authorized service institution or manufacturer.

Warning  Never connect or disconnect the leakage tester under water to avoid the penetration of liquid in the instrument and a subsequent repair.
5 Cleaning, Disinfecting and Sterilizing

5.1 Manual Reprocessing

Warning Prior to each insertion or immersion into any liquid you should carry out the leakage test as described in chapter 4.3

5.1.1 General

ACUTRONIC endoscopes are compatible with the disinfectants listed in chapter 8.1 Disinfectants, an extract of the List of procedures issued by the Disinfectant Commission in the Association for Applied Hygiene (VAH), dated 1st January 2006

Prepare a cleaning solution. Make sure to follow the guidelines of the cleaning agent’s manufacturer.

5.1.2 Cleaning

5.1.2.1 Preliminary Cleaning

Carry out the preliminary cleaning procedure immediately after the examination.

- As soon as you withdraw the endoscope after the examination, wipe the insertion tube with a single-use cloth for rough cleaning.
- Then, immerse the distal tip in a container filled with cleaning solution. Suck the cleaning solution through the working channel. At the same time, check the channel for free passage.
- Finally, draw the channel empty with air.

5.1.2.2 Leakage Test

Perform leakage test following the instructions of chapter 4.3 Leakage Test
5.1.2.3 Manual Cleaning

- To start with, prepare the cleaning solution as to the instructions of the manufacturer of the cleaning agent.

- After the leakage test, fully immerse the endoscope in a cleaning solution.

**Warning** Make sure to carry out all cleaning steps below the surface of the cleaning solution to avoid splashing of contaminated liquid.

- First, clean the outer casing of the endoscope with a lint-free single-use cloth.

- Then, clean the channel openings, the distal tip and the control elements using a soft brush.

- For mechanical cleaning, brush the working channel with a suitable, flexible, disinfected cleaning brush as many times as the brush is free of soil when pulling it through the channel.

- Now, connect the working channel with the irrigation tube and rinse them with the cleaning solution to remove all contamination particles.

- Finally, clean all cleaning brushes and disinfect them together with the endoscope.

5.1.2.4 Removing the Cleaning Solution

- Put the endoscope and accessories in a basin filled with clean tap water and rinse the channel to remove the cleaning agent.

- Then, air-blow the channel free.
5.1.3 Disinfection

5.1.3.1 Disinfecting

- First, fully immerse the cleaned endoscope and its accessories in disinfectant solution.
- Next, fill the channel and the irrigation tube with disinfectant solution avoiding bubbles.
- Then, remove the irrigation tube below the surface of the disinfectant solution.
- Put a tightly closing lid on the basin.

**Warning** Make sure to exactly keep the manufacturer’s instructions in terms of concentration and exposure time of the disinfectant.

- Mark the date of the preparation of the disinfectant solution on the basin.

**Warning** Changing the disinfecting basins, make sure to thoroughly clean them mechanically and disinfect them.

**Warning** Continually immersing the endoscope sheath in concentrated alcohol will cause irreversible deformations. If necessary, carry out a short wipe disinfection, however, make sure that the alcohol can evaporate after the wipe disinfection.

5.1.3.2 Final Irrigation

- To start with, remove the endoscope and its accessories from the disinfectant solution using single-use gloves.
- Air-blow the channel free.
- Insert the disinfected endoscope and its accessories in a container/basin filled with microbiologically proper/steril water. Make sure to use fresh water for each instrument.
- Rinse the outer casing of the endoscope and the channel thoroughly with microbiologically proper/steril water.
- Rinse the accessories clear under water.

5.1.3.3 Drying

- Finally, dry-blow the channel with air-pressure thoroughly.
- Dry the outer casing of the endoscope with a single-use cloth.
- Carry out a function test of the endoscope.

The endoscope is now ready for use with a patient.
5.2 Machine Reprocessing

Follow the guidelines of the manufacturer of the cleaning disinfection machinery for endoscopes. The max. reprocessing temperature is 60°C.

**Warning** Prior to each insertion or immersion into any liquid you should carry out the leakage test as described in chapter 4.3 Leakage Test.

5.3 Sterilization

5.3.1 STERIS® Sterilization

Follow the instructions of Steris Corporation attached to their sterilization equipment.

5.3.2 Ethylene Oxide Sterilization (ETO)

**Warning** First, connect the ETO cap and carry out the ETO sterilization keeping the following parameters:

- Max. temperature 60°C
- Pressure 1.0 – 1.7 kg/cm$^2$ (24 PSI)
- Depression 165 mmHg
- Max. humidity 50%
- Max. time four hours
- Ventilation time: seven days at room temperature, 12 hours in a ventilation chamber at 50 – 55°C

**Warning** Having finished the gas sterilization, remove the ETO cap to re-establish the instrument’s water tightness.
6 Maintenance and Service

6.1 User Maintenance

6.1.1 General
The intubation endoscope is maintenance free for their users.

6.1.2 Transport
The instrument should be transported only in its original packing. In the case of air transport, the ETO cap should be mounted to the connector for the leakage tester.

6.1.3 Storage
Make sure to thoroughly dry or sterilize the instrument and its accessories before storing them. Keep the instrument lying or hanging outside the transport case with dust protection. The insertion channel should be linearly stretched.

The storage room should be well ventilated, dry and have a temperature of 18 – 22°C.

6.2 Manufacturer’s Service
ACUTRONIC Medical Systems AG products and components must not be maintained and repaired by any person or institution other than ACUTRONIC Medical Systems AG or personnel authorized by them. Only original spare parts must be used for replacement.

Service Address:
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Fabrik im Schiffli
CH – 8816 Hirzel
Tel: +41 (0) 44 729 70 80
Fax: +41 (0) 44 729 70 81
E-mail: support@acutronic-medical.ch
Web: www.acutronic-medical.ch

If you have any requests or would like to order replacement articles, please state the type and serial number of your equipment.

Warning When you open the intubation endoscope, perform any repairs or changes on your own, any guarantee by ACUTRONIC Medical Systems AG for the specified performance, operation safety and damage will expire.

Warning Make sure to clean and disinfect the instrument prior to shipping them to the manufacturer for repair considering the instructions in chapter 4.3 Leakage Test.
6.3  Spare Parts and Accessories

6.3.1  Spare Parts

<table>
<thead>
<tr>
<th>Item</th>
<th>Item No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leakage Tester</td>
<td>130 009 012</td>
</tr>
<tr>
<td>ETO cap</td>
<td>130 009 010</td>
</tr>
<tr>
<td>Adapter type STORZ/OLYMPUS</td>
<td>110 221 110</td>
</tr>
<tr>
<td>Adapter type WOLF</td>
<td>110 221 120</td>
</tr>
<tr>
<td>Stop cock for suctioning</td>
<td>600 009 002</td>
</tr>
<tr>
<td>Cleaning brush Ø 1.5mm, length 1100mm, wire Ø 1mm</td>
<td>207 110 315</td>
</tr>
<tr>
<td>Cap for working channel</td>
<td>200 009 005</td>
</tr>
<tr>
<td>Irrigation tube</td>
<td>200 009 006</td>
</tr>
</tbody>
</table>

6.3.2  Accessories Recommended

We recommend that you use the following accessories for the EF-I14:

<table>
<thead>
<tr>
<th>Item</th>
<th>Item No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibre-optic light guide cable, Ø 3.5mm, length 1,80 m</td>
<td>310 722 318</td>
</tr>
<tr>
<td>Adapter for fibre-optic light-guide cable, light-source end, type STORZ</td>
<td>310 726 310</td>
</tr>
<tr>
<td>Adapter for fibre-optic light-guide cable, light-source end, type WOLF</td>
<td>310 727 320</td>
</tr>
<tr>
<td>Adapter for leakage tester, type OLYMPUS/ACUTRONIC</td>
<td>130 009 013</td>
</tr>
</tbody>
</table>

7  Technical Data

<table>
<thead>
<tr>
<th>Intubation Endoscope</th>
<th>Item No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>EF-I14</td>
<td>600 014 040AC</td>
</tr>
<tr>
<td>Sheath diameter</td>
<td>4,0 mm</td>
</tr>
<tr>
<td>Working length</td>
<td>600 mm</td>
</tr>
<tr>
<td>Bending angle</td>
<td></td>
</tr>
<tr>
<td>Up / down</td>
<td>180° / 130°</td>
</tr>
<tr>
<td>Bending radius</td>
<td>8 mm</td>
</tr>
<tr>
<td>Optical System</td>
<td></td>
</tr>
<tr>
<td>Field of view</td>
<td>110°</td>
</tr>
<tr>
<td>Depth of field</td>
<td>1 – 50 mm</td>
</tr>
<tr>
<td>Weight</td>
<td>230 g</td>
</tr>
</tbody>
</table>
### Appendix

#### 8.1 Disinfectants

Disinfectant solutions for manual reprocessing

<table>
<thead>
<tr>
<th>Hersteller, Vertrieb / manufacturer, distributor / Fabricant, distributeur</th>
<th>Handelsname / name / Nom</th>
<th>Wirkstoffbasis / active ingredients / Matières actives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acto® GmbH</td>
<td>actosed endo</td>
<td>Alkylaminindervat, quaternäre Verbindung / alkyamine derivate, quaternery compound / Dérivé d’alkylamine, composant quaternaire</td>
</tr>
<tr>
<td>Acto® GmbH</td>
<td>Actosed Endo Terra</td>
<td>Quaternäre Verbindung, Guanidinderivate / quaternery compound, guanidine derivate / Composant quaternaire, dérivé de guanidine</td>
</tr>
<tr>
<td>Advanced Sterilization Products</td>
<td>Cidezyme</td>
<td></td>
</tr>
<tr>
<td>Bode Chemie GmbH &amp; Co.</td>
<td>Aseptisol®</td>
<td>Aldehyde, quaternäre Verbindung / aldehyde, quaternery compound / Aldéhyde, composant quaternaire</td>
</tr>
<tr>
<td>Bode Chemie GmbH &amp; Co.</td>
<td>Bodedex forte</td>
<td></td>
</tr>
<tr>
<td>Bode Chemie GmbH &amp; Co.</td>
<td>Korsolex® AI</td>
<td>Alkylamine / alkyamine / alkyamine</td>
</tr>
<tr>
<td>Bode Chemie GmbH &amp; Co.</td>
<td>Korsolex® basic</td>
<td>Aldehydbasqspter, Aldehyd / Aldéhydabspalter, aldehyde / Aldéhyde, dérivé d’aldehyde</td>
</tr>
<tr>
<td>Bode Chemie GmbH &amp; Co.</td>
<td>Korsolex® extra</td>
<td>Aldehydbasqspter, Aldehyd, quaternäre Verbindungen / Aldéhydabspalter, aldehyde, quaternery compound / Dérivé d’aldehyde, aldéhyde</td>
</tr>
<tr>
<td>Bode Chemie GmbH &amp; Co.</td>
<td>Korsolex® FF</td>
<td>Aldehyd, quaternäre Verbindung / aldehyde, quaternery compound / Aldéhyde, composant quaternaire</td>
</tr>
<tr>
<td>Bode Chemie GmbH &amp; Co.</td>
<td>Korsolex® plus</td>
<td>Quaternäre Verbindung, Alkylamin / quaternery compound, Alkylamin / Composant quaternaire, alkyamine</td>
</tr>
<tr>
<td>Borer Chemie AG</td>
<td>deconex® 53 Plus</td>
<td>Quaternäre Verbindung, Guanidinderivate / quaternery compound, guanidine derivate / Composant quaternaire, dérivé de guanidine</td>
</tr>
<tr>
<td>Chemische Fabrik Dr. Weigert (GmbH &amp; Co.)</td>
<td>neodisher® Septo 3000</td>
<td>Aldehydbasqspter, Aldehyd / Aldéhydabspalter, aldehyde / Aldéhyde, dérivé d’aldehyde, aldéhyde</td>
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<td>Chemische Fabrik Dr. Weigert (GmbH &amp; Co.)</td>
<td>neodisher® Septo Med</td>
<td>Quaternäre Verbindung, Alkylamin / quaternery compound, Alkylamin / Composant quaternaire, quaternery compound / Aldéhyde, composant quaternaire</td>
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<td>Desomed Dr. Trippen GmbH</td>
<td>Desomedan Septo Med</td>
<td>Quaternäre Verbindung, Guanidinderivate / quaternery compound, guanidine derivate / Composant quaternaire, dérivé de guanidine</td>
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<tr>
<td>Dr. Schumacher GmbH</td>
<td>Descoton forte •1</td>
<td>Aldehyd / aldehyde / Aldéhyde</td>
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<tr>
<td>Dr. Schumacher GmbH</td>
<td>Descoton Plus</td>
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<tr>
<td>Dr. Schumacher GmbH</td>
<td>Perfektan Endo</td>
<td>Quaternäre Verbindung, Guanidinderivate / quaternery compound, guanidine derivate / Composant quaternaire, dérivé de guanidine</td>
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<tr>
<td>Ecolab GmbH &amp; Co OHG/ Ecolab Deutschland GmbH</td>
<td>Sekusept® extra N</td>
<td>Aldehyd, quaternäre Verbindung / aldehyde, quaternery compound / Aldéhyde, composant quaternaire</td>
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<tr>
<td>Ecolab GmbH &amp; Co OHG/ Ecolab Deutschland GmbH</td>
<td>Sekusept® forte</td>
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<td>Ecolab GmbH &amp; Co OHG/ Ecolab Deutschland GmbH</td>
<td>Sekusept® forte S</td>
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<td>Ecolab GmbH &amp; Co OHG/ Ecolab Deutschland GmbH</td>
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<td>Ecolab GmbH &amp; Co OHG/ Ecolab Deutschland GmbH</td>
<td>Sekusept® Pulver + Aktivator</td>
<td>Peroxidverbindung / peroxide compound / composant péroxyde</td>
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<td>Ecolab GmbH &amp; Co OHG/ Ecolab Deutschland GmbH</td>
<td>Sekusept® Pulver classic + Aktivator</td>
<td>Peroxidverbindung / peroxide compound / composant péroxyde</td>
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<tr>
<td>Ethicon GmbH</td>
<td>Cidex® OPA Instrumenten-Desinfektionsmittel</td>
<td>Aldehyd / aldehyde / Aldéhyde</td>
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### Disinfectant solutions for machine reprocessing

<table>
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<tr>
<th>Hersteller, Vertrieb / manufacturer, distributor / Fabricant, distributeur</th>
<th>Handelsname / name / Nom</th>
<th>Wirkstoffbasis / active ingredients / Matières actives</th>
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<td>Almyrol®</td>
<td>Alkylaminoderviat, Guanidinderivate, quaternäre Verbindung / alkyamine derivate, guanidine derivate, quaternery compound / Dérivé d’alkylamine, dérivé de guanidine, composant quaternaire</td>
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<td>Desoform®</td>
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<td>Lysoformin® 2000</td>
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<td>Lysoform Dr. Hans Rosemann GmbH</td>
<td>Lysoformin® 3000</td>
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<td>medichem</td>
<td>medichem instrumentendesinfektion</td>
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<td>Mucadont®-IS</td>
<td>Aldehyde / aldehyde / Aldéhyde</td>
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<td>Merz Consumer Care GmbH Bereich Hygiene</td>
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<td>Phenolderivate / phenol derivate / Dérivé de phénol</td>
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<td>Merz Consumer Care GmbH Bereich Hygiene</td>
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<td>Quaternäre Verbindung, Guanidinderivate, Aldehyderivate / quaternery compound / Guanidine derivate, dérivé de guanidine</td>
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<td>Schülke &amp; Mayr GmbH</td>
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<td>Schülke &amp; Mayr GmbH</td>
<td>Gigasept® AF</td>
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<td>Schülke &amp; Mayr GmbH</td>
<td>Gigasept® FF</td>
<td>Aldehyde, Aldehydsäbpalsierer / aldehyde, Aldehydsäbpalsierer / Aldéhyde, dérivé d’aldehyde</td>
</tr>
<tr>
<td>Schülke &amp; Mayr GmbH</td>
<td>Gigasept® Med</td>
<td>Quaternäre Verbindung, Glykolderviat, Amphotenside / quaternery compound, glycol derivate, amphotensides</td>
</tr>
<tr>
<td>Schülke &amp; Mayr GmbH</td>
<td>Lysetol® AF</td>
<td>Glykolderviat, Guanidinderavit, quaternäre Verbindung / glycol derivate, guanidine derivate, quaternery compound / Dérivé de glycol, dérivé de guanidine, composant quaternaire</td>
</tr>
<tr>
<td>Schülke &amp; Mayr GmbH</td>
<td>Lysetol® V (neu)</td>
<td>Aldehyde, quaternäre Verbindung / aldehyde, quaternery compound / Aldéhyde, composant quaternaire</td>
</tr>
<tr>
<td>Tristel Solutions Ltd.</td>
<td>Tristel Generator Solution</td>
<td>Chlorindioxid / chlorine dioxide / Biocide de chlore</td>
</tr>
</tbody>
</table>

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