INSTRUMENTS
INSTRU ZYM, INSTRU SOL FORTE, INSTRU PLUS, INSTRU PLUS FORTE, ENDO STAR, INSTRU STAR, INSTRU STAR R.F.U., INSTRU SUC, INSTRU CARE, INSTRU GEL, ENDOMAT PLUS, LABOMAT E, LABOMAT SPM, LABOMAT MA LIQUID, LABOMAT KS,
Various products approved by Karl Storz, Richard Wolf and Pentax

SURFACES
SPRAY IN, SPRAY OFF N, TOP OFF, ACETAL COMBI, ALPHA GUARD, BETA GUARD

HANDS AND SKIN
LOTIO LIND, LOTIO C PLUS, OP-SEPT MEDICAL, OP-DERM MEDICAL, LOTIO SEPT GEL, LOTIO MED, LOTIO MED SCRUB, LOTIO SEPT WIPES, LOTIO HD

CLEANSING
DISINFECTION
CARE

Laboratorium Dr. Deppe
D-47906 Kempen
Germany
www.dr-deppe.de

2007
Disinfection:
Disinfectants for re-processing of instruments are medical products of the class 2 a. These products have to be in accordance with the regulations and need certification. DIN EN norms and the standard methods of the German Society for Hygiene and Microbiology (DGHM) as well as the recommendation of the Federal German Robert Koch Institute (RKI) describe the correspondent state-of-the-art. Microbial effectiveness which means bactericidal, fungicidal, tuberculocidal, virucidal incl. HBV/HIV has to be proved by expert opinion reports. Definition: after disinfection 1 of 100,000 germs may survive, after sterilisation 1 of 1 Mio.

Wide ranged experiences with the use of disinfectants based on aldehydes exist for a long time. But they tend to coagulations and are not to be used in the cleansing step. For the disinfection of medical products of the group “semi critical B” however, which can not be vapour sterilized, like e.g. flexible cystoscopes, aldehyde based disinfectants or disinfectants based on peracetic acid are to be preferred. Aldehyde-free formulas are being used only for a few years. They show advantages concerning expositions and are to be preferred for the ultra sonic reprocessing. Concentrates are being preferred to ready-to-use products due to their economical advantages. Manufacturers’ recommendations should be followed concerning material toleration, dosage and usage.

Efficacy against viruses:
The efficacy against enveloped viruses (limited virucidal) is distinguished from the efficacy against enveloped and non-enveloped viruses (virucidal). HBV, HCV and HIV belong to the enveloped viruses and the infection risk with HBV is considered as especially high. The evaluation of the efficacy against HBV is difficult, because cell cultures are not available for the sensitive, direct verification. A reliable alternative is the infection test with DHBV, which is internationally recognized and which has proven fully satisfactory. The DHBV virus is similar to the HBV virus of the human being, very well investigated and not human pathogen.

Cleaning:
Thorough and residue-free cleaning is a pre-condition for a perfect reprocessing. Particularities of the construction of the instrument and sensitive materials complicate a proper cleansing. Sediments of organic dirt like albumen and protein are reasons for an imperfect hygienic outcome of the reprocessing. Non-organic sediments as pharmacologic adhesions, radiopaque material and bio-films complicate the cleansing additionally.

Inadequate cleaning, which means negative effects such as e.g. coagulations, encrusts, fixation of detritus, might lead to unsatisfactory hygienic results. The consequences are:

- insufficient hygienic and disinfecting results
- impaired functions
- material damages
**Reprocessing steps:**

A proper and correct reprocessing of instruments consists of the following steps:

- to disassemble instruments
- cleansing (prevent that the worker does get infected during this step by using anti-microbial detergents like INSTRU ZYM !!)
- disinfection (manually or mechanically)
- rinsing with germ free water
- drying
- examination of the function of the instrument
- labelling
- packaging
- sterilisation (if the instrument material allows it)
- documentation and approval/clearance

**Enzymatic cleaner:**

Enzymatic cleaners based on proteases and amylases have various advantages. They digest and dissolve substances such as blood, fat, protein, albumin, mucous, detritus and all organic contaminants. They avoid coagulation as well as bio-films. Enzymatic detergents have proven effective especially for the cleansing of rigid and flexible endoscopes, endoscope accessories and orthopaedic instruments.

Some manufacturers add the third enzyme **lipase** to their detergents, but this does technically not make any sense. The lipase enzyme starts working only at 60°C, but the other two enzymes **protease** and **amylase** lose their efficacy already beyond 50°C.

**Fiberscopes:**

Flexible endoscopes always have to be cleaned thoroughly before disinfection takes place, either manual or mechanical disinfection.

A density test is compulsory before thorough cleaning is performed.

Channels need to be brushed thoroughly. Brushing with water only is not sufficient. Enzymatic cleaners are generally recommended. Manufacturers’ recommendations should be followed.

Rinsing: water for the **final rinse** (after disinfection) should consist of at least **drinking water quality, preferably sterilised water**, in order to prevent from re-contamination with germs.

**Drying**: Insufficient drying causes bio-films, which means contamination with pseudomonas. Drying should take place according to manufacturers’ recommendations by using a certain amount of compressed air.

**Endoscopy Accessories:**

Thorough cleaning is a pre-condition for sterilisation or disinfection of re-usable accessories such as forceps et cetera. The cleaning result is improved by the use of ultrasonic as well as enzymatic cleaners. Manufacturers’ recommendations have to be observed in order to avoid possible material damages. Standard parameters for ultrasonic cleaning are frequencies between 35 - 45 kHz with duration of 5 - 10 min and water temperatures of maximal 40°C to 45°C.
Surgical instruments / Instruments made of metal:

The water quality is an important factor concerning the maintenance of metallic instruments. The water consistency is of great interest as water might contain unfavourable mineral substances (salts, chloride, magnesium, iron, copper etc.) which as a result could lead to the creation of residues, discoloration or corrosion. Especially chlorides should be regarded in a critical way. Experience shows that corrosion is likely to increase if chloride concentrations are higher than 120 ml/l. The final rinse before the sterilisation process (especially in case of vapour sterilisation) should be performed by using demineralised water.

Maintenance and care:

Surgical instruments:

An oil-spray should be used (INSTRU CARE) in order to ensure the maintenance and function of articulated instruments. The oil should be physiologically harmless, should not affect the sterilisation result, should be temperature stable and leave no residue.

Anti-friction gel for fiberscopes:

The purpose of the anti-friction gel INSTRU GEL is to relieve the examination for the patient and to protect the fiberscope from damage. The anti-friction gel has to be water soluble.

Protective clothing:

Protective clothes should be worn (protection of staff) during the re-processing of instruments:

- latex gloves
- protective glasses/shields
- protective face masks
- special examination gown or coat (long sleeved, moisture resistant) or plastic aprons with sleeves

Characteristics of an ideal instrument disinfectant:

Wide range of spectrum of effect; rapid action; compatible with instrument materials as metal, plastic, rubber; slight or no odour; economical; well cleansing; easy to use and to dilute; soluble in water; biodegradable;

Notice:

The recommendations to our preparations are based on scientific examinations and are issued to our best knowledge. Further recommendations, for example for special material compatibility are only possible separately. Our recommendations do not exempt our customers from their own examination of the individual application purpose of our product.
Certificate

Quality Assurance

ecm, Eifelstr. 1c, 52068 Aachen hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of DIN EN ISO 9001:2000. Through an audit performed on behalf of

Laboratorium Dr. Deppe

at the manufacturing site

Hoogheweg 35
D-47906 Kempen

it could be demonstrated that a quality assurance system for the manufacture and distribution of disinfectants and accessories to medical devices according to DIN EN ISO 9001:2000 has been established and implemented.

This certificate is only valid under the conditions stated in the hereafter mentioned audit report. Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report Number Registered under Valid until
128-06-410 2/06/01156 08.06.2011

Aachen, 2006-06-08

[Signature]

Certification Body
Certificate

Quality Assurance

dcm, Eifelstr. 1c, 52068 Aachen hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2003.

Through an audit performed on behalf of

Laboratorium Dr. Deppe

at the manufacturing site

Hoogheweg 35
D-47906 Kempen

it could be demonstrated that a quality assurance system according to DIN EN ISO 13485:2003 "Medical devices – Quality management systems – Requirements for regulatory purposes" for the manufacture and distribution of disinfectants and accessories to medical devices has been established and implemented.

This certificate is only valid under the conditions stated in the hereafter mentioned audit report. Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report Number Registered under Valid until
128-06-410 Z/06/01155 08.06.2011

Aachen, 2006-06-08
Certificate

Production Quality Assurance System Approval
Annex V of the Directive on Medical Devices

ECM notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex V of the Directive 93/42/EEC.

This certificate is issued on behalf of:

Manufacturer
Laboratorium Dr. Deppe
Hoogheweg 35
D-47806 Kempen

ECM certifies that the quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex V of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex V of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Report Number  Registered under  Valid until
Z128-001     Z/03/00467     10.06.2007

Aachen, 2004-06-24

[Signatures]

Lead Auditor  Certification Body
Supplement to Annex I of Certificate Z/03/00467
from 2003-06-16
Number of Pages: 1

The hereafter following devices have been subject to further approval:

<table>
<thead>
<tr>
<th>Name of product category</th>
<th>Name of individual type</th>
<th>Nomenclature code</th>
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<td>Single use device</td>
<td>Desinfecting Units,</td>
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<td>Liquid, Flexible</td>
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Special terms of validity:
None.

Supplement to Annex I of Certificate Z/03/00467
from 2004-06-24
Number of Pages: 1

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<td>Dental, Other</td>
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Annex I to Certificate Z/03/00467
Number of Pages: 1

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<tbody>
<tr>
<td>Single use device</td>
<td>Lubricating Jellies</td>
<td>12-491</td>
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</table>

Special terms of validity:
None.
**INSTRU ZYM** (concentrate)

**enzymatic detergent**

Complies with the requirements of the Robert Koch Institute for the profound manual pre-cleansing. Safe and economical.

Medical product of the class I, CE
Article number 90001 (1-litre bottle), 90002 (5-litre canister), 90003 (150ml bottle)

**Type of preparation:**
INSTRU ZYM is an enzymatic cleaner for the material caring, residue free cleaning of medical instruments, especially of flexible and rigid endoscopes, endoscope accessories as well as of surgical and orthopaedic instruments. Special, highly active enzymes, supported by an innovative system of surfactants, remove sediments of blood, secretions, detritus, rest of tissues and fat. Polysaccharide-splitting enzymes prevent bio-films, which harbour dangerous pathogenic germs which are very difficult to eliminate and which are extremely resistant to disinfectants. With an effective, residue free cleaning in 2 - 3 minutes and its bacterial and virus inactivating qualities INSTRU ZYM provides for the optimal precondition for an effective disinfection and sterilization. INSTRU ZYM prevents coagulations and therefore minimizes instrument failures and ensures the functioning of movable instrument parts. **Important for endoscopes and endoscopes accessories.**

Tested and released for material compatibility by three leading endoscope manufacturers of the world: Karl Storz (Germany), Richard Wolf (Germany), Pentax (Japan).

**Certification** by University and Scientific Institutes expert opinions (latest ones):
**Micro-biological and virological expert opinions:**
BVDV (HCV), VACCINIA
Dr. Steinmann, Bremen 2005
HBV/HIV inactivation:
Dr. Steinmann, Bremen 2000
Bactericidal according to EN 1040
Dr. J. Höf fler, Institute for Technical Microbiology 2002
Tests for the cleansing properties:
Degradation of bio-film of Pseudomonas aeruginosa:
Dr. Seipp, HSK Wiesbaden 1999
Elimination of fibrins:
PEREG GmbH, Waldkraiburg 2001

**Dosage and usage:** 0,5 - 3 % according to the degree of soiling (2 - 3 minutes). If the instruments are cleaned after each use with INSTRU ZYM 1 - 3 % are sufficient. If needed, the concentration can be increased to 5 %. The usage solution can be used several times, but has to be renewed regularly. Under normal conditions the usage solution has to be renewed 1 - 2 times a day. With extreme dirt and low concentrations we recommend renewing the solution after each reprocessing. **With a dosage of 3% (5 minutes) INSTRU ZYM has also got disinfecting properties (but does not replace a disinfectant).**

3% (30ml) concentrate + 100 % (1 litre) water effective time 2-3 minutes
3 % (150ml) concentrate + 100 % (5 litres) water - effective time 2-3 minutes
- for this quantity we offer a 150ml bottle: the user simply pours the contents in a standard tub with 5 litres of water avoiding like this problems and complications with the dosage procedure.

**Available Sizes:**

- 1-litre bottle,
- 5-litre canister,
- 150ml portion - bottle (other filling units on demand)

**Shelf life:**
2 years

**Reuse life:**
can be used several times, but should be renewed 1 - 2 times a day

**Instruments**
manual treatment of instruments

**Spectrum of effect:**
BVDV (HCV), Vaccinia, HBV, HIV, prevents biofilms, anti-microbial (effective against all enveloped viruses)

**Main advantages:**
+ very material caring even with sensitive materials; + ph value neutral; + Supported by an effective system of surfactants proteases and amylases split and suspend protein, albumen, fat and polysaccharides; + ideal for the reprocessing in the ultra sonic bath, foamless; + effective with all water temperatures, warm water improves the cleaning effect (30 - 45°C); + prevents bio films and minimizes formation of new germs; + a bactericidal and virus inactivating component protects while handling with the dirty usage solution, but does not replace disinfectants; + economical through low usage concentrations.

**Ingredients:**
Proteases, amylases, glycols, non-ionic surfactants, preservatives, perfumes, cleaned water, corrosion inhibitors.

**Certification** by University and Scientific Institutes expert opinions (latest ones):
**Micro-biological and virological expert opinions:**
BVDV (HCV), VACCINIA
Dr. Steinmann, Bremen 2005
HBV/HIV inactivation:
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Tests for the cleansing properties:
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Dr. Seipp, HSK Wiesbaden 1999
Elimination of fibrins:
PEREG GmbH, Waldkraiburg 2001
Manual reprocessing, ultra sonic bath and circulation method:
Immerse instruments after use. All surfaces and hollows must be covered and filled. Clean the instruments thoroughly and pay attention to the instructions of the instrument manufacturers. With encrusting: let INSTRU ZYM work preferably with warm water The product is stable until maximal 50°C. In the ultra sonic bath: stick to the given frequencies and working time. Avoid temperatures above 45 °C. Afterwards take out the instruments and disinfect them. For disinfection we recommend ENDO STAR, INSTRU PLUS or INSTRU STAR. INSTRU ZYM has also shown excellent results when used for the cleaning of bed linen and laundry. Add 3-5% to the pre-washing step at not more than 40°C and you will get snow white and partially disinfected cloths.

Application hints:
The directions for use and the reprocessing guidelines of the manufacturers of the instruments, the endoscopes, the endoscope accessories and of the reprocessing equipments have to be absolutely followed; especially the instructions concerning the preparing measures for the cleansing procedure. For the disinfection we recommend INSTRU PLUS, ENDO STAR INSTRU PLUS FORTE or INSTRU STAR.

Compatibility / Water quality: INSTRU ZYM is compatible with the aldehyde free disinfectants ENDO STAR and INSTRU STAR. Intermixture with aldehyde containing disinfectants does generally not make sense because it would destroy the enzymes. INSTRU ZYM is preferably to be stored cool. Storage temperatures above room temperature and direct solar radiation are to be avoided. INSTRU ZYM is effective with all water temperatures, also with cold water. Warm water accelerates the cleaning performance. The optimal working temperature is between 30°C and 45°C. Drinking water is necessary for the preparation of the solution. If the drinking water is very hard, we recommend distilled water.

Storage conditions: do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry
INSTRU SOL FORTE
Cleansing of instruments, concentrate

- new and improved formula of the former product Instru Sol
- anti-microbial
- complies with the requirements of the Federal German Robert Koch Institute for the profound manual pre-cleansing.

Safe and economical.
Medical product of the class I, CE
Article number 90010 (2-litre bottle), 90011 (5-litre canister)

Type of preparation:
INSTRU SOL FORTE is a new detergent - active on surfaces - for the material caring reprocessing of thermostable and thermolabile medical instruments and laboratory objects. A special system of surfactants and synergistic supplementing complex building agents dissolves organic dirt from instruments, like blood, protein, secretions, fat -, but especially also non organic dirt, like radiopaque material and bio-films.

Properties of the product:
· dissolves and eliminates persistent organic and non organic dirt, especially also strongly adhering radiopaque material and bio-films
· to be used perfectly also with hard water
· material caring
· residue free
· foam poor
· economical
· perfume and colorant free
· an anti-microbial component protects the worker while handling the usage solution

Usage:
0,5 - 1% according to the degree of dirt and application. If necessary the concentration can be increased to 2%.
The usage solution can be used various times, but has to be renewed regularly. Under normal conditions the usage solution has to be changed 1 x 2 times a day. Under aggravated conditions and low usage concentrations we recommend renewing the solution after each reprocessing.

Hints for the application:
The usage instructions and reprocessing guidelines of the manufacturers of the instruments, laboratory devices and equipments are to be strictly followed, especially the preparing measures for the cleansing.

Hints for the reprocessing:
Immerse the instruments after use. All surfaces and hollow spaces must be covered resp. filled. Clean the instruments thoroughly and observe the instructions of the manufacturers of the instruments. With encrusting let INSTRU SOL FORTE act on the encrusted area and use preferably water at room temperature.

In the ultra sonic bath respect the given frequency and time of cleansing. Avoid temperatures above 45°C. Afterwards take out the instruments and disinfect them or rinse them thoroughly with water, dry them well and sterilize them.

INSTRU SOL FORTE is compatible with aldehyde based and aldehyde free instrument disinfectants.

A combination with other detergents and disinfectants is not recommended.
INSTRU SOL FORTE has to be stored preferably at room temperature.

For the preparing of the usage solution you must use water with drinking water quality. For the final rinse we recommend germ free or sterile water. For the final rinse before vapour sterilisation you must use fully desalted water or Aqua dest.
INSTRU PLUS (concentrate)

aldehyde based disinfectant

Medical product of the class IIa, CE 0481
Article number 90030 (2-litre bottle), 90031 (5-litre canister),
90032 (150ml bottle)

Type of product:
INSTRU PLUS is a classical, well tried, highly effective instrument disinfectant
which has gained confidence among countless users. It is based on a special
acetaldehyde formula with quaternary ammonium compounds. The very good
material compatibility and the low usage concentrations allow the
economical reprocessing of all thermostable and thermolable instruments, especially
of anaesthetic accessories, flexible endoscopes and endoscope accessories.
INSTRU PLUS is suitable for the manual reprocessing by immersion
and for the ultra sound bath (3% - 5 min) as well as for the reprocessing of flexible
endoscopes with the circulation method in so called half- and full automa-
tes. The excellent material compatibility is confirmed by numerous references
(also for acrylic layers).

Tested and released for material compatibility by three leading endoscope
manufacturers of the world: Karl Storz (Germany), Richard Wolf (Germany),
Pentax (Japan).

Tested according to the standard methods of the DGHM (German Society of
Microbiology and Hygiene), the EN-norms for disinfection of instruments (prEN
13624, prEN 13727, 14348, 14561, 14562, 14563) and according to the recom-
mendations of the Robert Koch Institute for the efficacy against viruses.

Certification by University and Scientific Institutes expert opinions:
Bactericidal, fungicidal incl. Aspergillus niger, tuberculocidal incl. M. Terrae, according
to the standard method of the DGHM and EN norms: (prEN 13624,
prEN 13727, 14348, 14561, 14562, 14563):
Hygiene Nord GmbH, Greifswald 2004
Standard method of the DGHM:
Prof. Dr. Schubert, Frankfurt 1985, 1993
Efficacy against covered viruses:
BVDV/ Vaccinia (1% - 15 min):
Dr. Steinmann, Bremen 2004
Parvo (screening test):
Eurovir, Greifswald 2004
Efficacy against uncovered viruses:
Polio 6% - 240 min, Adeno 2% - 15 min, Papova, SV40 2% - 120 min
Dr. Steinmann, Bremen 2005
Efficiency against HBV/HIV:
Prof. Dr. med. G. Frösner, Munich 1986
Microbiological test report:
J. G. A. Immink, Arnheim 1998
Tuberculocidal test report (Mycobacterium terrae ATCC 15755; 2% - 15 min)
PD Dr. med. F.- A. Pitten, Giessen 2006
Tuberculocidal test report (Mycobacterium terrae ATCC 15755;
2% - 15 min; 3% - 5 min)
Hygiene Nord GmbH, Greifswald 2004
Test report on DHBV/Hepatitis B efficacy ( 2% - 15 min)
Dr. med. Vet. O. Thraenhart, Luckenwalde 2005

Main advantages:
+ highly effective with 1, 2 or 3 %; + pleasant
smell; + powerful cleaning; + very economi-
cal, + excellent material compatibility, + bio-
logically degradable, + good skin tolerance
with unintended short-contact.

Active ingredients
100 gr contain:
5,27g Formacetal,
3,50g Ethandial (Glyoxal),
0,95g Formaldehylde (Methanal),
4,90g Glutardialdehyde (Pentandial),
3,50g Alkyldimethylammoniummethosulfate,
other ingredients: surfactants, corrosion inhi-
bitors, preservatives, ph-value regulators.

Available Sizes: CE0481
150ml portion bottle, 2-litre bottle and 5-litre
canister (other filling units on demand)

Chemical and physical data:
Appearance: clear, green liquid
Odour: aromatic, aldehyde like
Density: 1,047 - 1,057 g / cm³
nD²⁰: 1,365 - 1,370
PH-value: 4-5
PH-value of the 1%-usage solution: ca. 7

Shelf life:
3 years
Dosage and usage: to be diluted in distilled or at least drinking water (best: 20-25°C). Immerse the instruments immediately after use. All surfaces and hollow spaces have to be covered resp. filled. Pay attention to the application concentrations and the working times. Take out the instruments, rinse them thoroughly with water and dry them.

Before the disinfection the instruments have to be cleaned (preferably with the enzymatic cleaner INSTRU ZYM).

Usage concentrations according to DGHM/EN (incl. M. terrae, M. Avium, A. Niger):

1% (10ml) concentrate + 100% (1 litre) water - effective time 1 hour
2% (20ml) concentrate + 100% (1 litre) water - effective time 30 min
3% (30ml) concentrate + 100% (1 litre) water - effective time 15 min

3% (150ml) concentrate + 100% (5 litres) water - effective time 15 min
- for this quantity we offer a 150ml bottle: the user simply pours the contents in a standard tub with 5 litres of water avoiding like this problems and complications with the dosage procedure.

For cold sterilisation: 5% - 5 hours.

Drinking water can be used for the final rinse if it does not contain pathogen germs, otherwise distilled water. If the water is very hard or if its chloride content is high, we recommend for the final rinse fully desalted water.

The Instru Plus usage solution does not lose its efficiency in the presence of protein (blood) and can therefore be used several times. When immersing well pre-cleaned instruments the solution can be effective at least until 7 days. However, if the solution becomes turbid it should be changed (the effectiveness can be tested with formaldehyde test strips).

Storage conditions: do not allow temperatures below 0°C or above 30°C; do the product not expose to direct sunlight; keep the store dry
INSTRU PLUS FORTE (concentrate)
aldehyde based disinfectant, formaldehyde free

Medical product of the class IIa, CE 0481
Article number 90050 (2-litre bottle), 90051 (5-litre canister)

Type of product:
INSTRU PLUS FORTE is a recently developed, highly effective instrument disinfectant based on acetals and aldehydes (but without formaldehyde). The very good material compatibility and the low usage concentrations allow the economical reprocessing of all thermostable and thermolable instruments, especially of anaesthetic accessories, flexible endoscopes and endoscope accessories. INSTRU PLUS FORTE is suitable for the manual reprocessing by immersion and for the ultra sound bath as well as for the reprocessing of flexible endoscopes with the circulation method in so called half- and full automates.

INSTRU PLUS FORTE is tested according to the standard methods of the DGHM (German Society of Microbiology and Hygiene), the EN-norms for disinfection of instruments (prEN 13624, 13727, 14348, 14561, 14562, 14563) and according to the recommendations of the Robert Koch Institute for the efficacy against viruses.

Certification by University and Scientific Institutes expert opinions:
Bactericide, fungicide, tuberculocide incl M. Terrae
According to standard method of the DGHM and EN:
(prEN 13624, 13727, 14348, 14561, 14562, 14563):
Hygiene Nord GmbH, Greifswald 2004
Prof. Dr. Schubert, Frankfurt 2003

Efficacy against covered viruses,
BVDV/ Vaccinia:
Dr. Steinmann, Bremen 2004

Main advantages:
- bactericidal, fungicidal, tuberculocidal (incl. M. Terrae)
- effective against all covered and uncovered viruses
- formaldehyde free
- very economical through very low usage concentrations (1 - 1.5%)
- good cleaning properties
- pleasant in smell
- excellent material compatibility
- good skin tolerance with unintended short contact with the usage solution
- biologically well degradable

Dosage and usage:
For all areas where medical instruments are cleaned and disinfected; by the immersion method, by the circulation method at normal water temperatures (25°C) and in the ultra sound bath (2% - 5 min).

Immersion method:
rsion method:
Immerse the instruments immediately after use. All surfaces and hollow spaces have to be covered resp. filled. Pay attention to the application concentrations and the working times. Take out the instruments, rinse them thoroughly with water and dry them.

Circulation method with endoscopes:
The directions for use of the manufacturers of the equipments have to be followed, especially the indications regarding dosage adjustments, the sequences of the programs and the change of preparations. If in the sequence of the program a cleaning step is not included or not sufficiently included, we recommend
for the manual pre-cleaning of endoscopes the enzymatic cleaner INSTRU ZYM. After the disinfection a sufficient final rinse and a sufficient drying have to be done.

**Compatibility / Stability / Quality of the water:**
For the preparation of usage solutions and for the rinsing you must use water with potable water quality. If the acceptable maximum number of germs in the drinking water is exceeded or if there are pathogen germs, you have to use for the rinsing step germ free or sterilized water. If the drinking water is very hard or if the chloride content is high we recommend desalinated water or Aquadest.

For the rinsing step before sterilisation you have to use fully desalinated water (VE). The INSTRU PLUS FORTE usage solution withstands protein and can be used several times. The usage solution is stable until 7 to 14 days if well pre-cleaned instruments are immersed. If the usage solution gets turbid or if there is visible dirt it has to be changed earlier. If surfactant cleaners are used they must contain exclusively non-ionic surfactants and they should be pH-neutral, like for example INSTRU SOL. For the pre-cleaning of endoscopes, accessories, surgical and especially hollow instruments and instruments with narrow channels and with heavy dirt we recommend the enzymatic cleaner INSTRU ZYM. If you add cleaners the usage solution has to be renewed every day.

**Change of preparation:**
INSTRU PLUS FORTE is not compatible with aldehyde free disinfectants. When you use it for the first time and when you change the preparation all the instruments, accessories, the tubs and the reprocessing equipments and the applications aids have to be thoroughly cleaned and rinsed. For a better cleaning we recommend the cleaner INSTRU SOL.

**Chemical-thermal reprocessing of endoscopes:**
If endoscopes are reprocessed manually and mechanically or if there is a disinfecting pre-cleaning step, INSTRU PLUS FORTE can also be used for the pre-cleaning. At this INSTRU PLUS FORTE is not compatible with INSTRU ZYM.

**Usage concentrations according to DGHM/EN:**

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Usage Solution</th>
<th>Water</th>
<th>Effective Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1%</td>
<td>(10ml) concentrate + 100% (1 litre) water</td>
<td>effective time 30 min</td>
<td></td>
</tr>
<tr>
<td>1.5%</td>
<td>(15ml) concentrate + 100% (1 litre) water</td>
<td>effective time 15 min</td>
<td></td>
</tr>
<tr>
<td>3%</td>
<td>(30ml) concentrate + 100% (1 litre) water</td>
<td>effective time 05 min</td>
<td></td>
</tr>
</tbody>
</table>
Zertifikat / Certificate

verbund für
Angewandte Hygiene (VAH)
Association for Applied Hygiene
Deutsche Gesellschaft für
Hygiene und Mikrobiologie (DGHM)
German Society for Hygiene and Microbiology
— Desinfektionsmittel-Kommission im VAH —
Disinfectant Commission in VAH

Inhaltsfortsetzung
mit dem Anforderungsakt der Deutsche Gesellschaft für Hygiene und Mikrobiologie (DGHM) - Stand 4.2.2002 - 
bestehend auf den Standardproben der DGHM - Stand 1.9.2001 - bzw. den Oberflächenformularen vom 4.9.2002
DGHM und VAH bestätigten die Äquivalenz mit den früher herausgegebenen DGHM-Zertifikaten

ANTRAGsteller / APPLICANT: Laboratorium Dr. Seippe
Hoogheweg 35
47906 Kempen

Inhalt: Desinfektionsmittel

Title: Disinfectant product

Gültigkeit: 3 Jahre nach Ablauf der Gültigkeitszeit

Table:

<table>
<thead>
<tr>
<th>Organism / Organismus</th>
<th>Effektivität</th>
<th>Min. Kontaktzeit</th>
</tr>
</thead>
<tbody>
<tr>
<td>H. influenzae</td>
<td>2.0%</td>
<td>15 min</td>
</tr>
<tr>
<td>M. tuberculosis</td>
<td>1.5%</td>
<td>60 min</td>
</tr>
</tbody>
</table>

Das Zertifikat löst am 22.12.2006 (3 Jahre nach Ablauf der Gültigkeitszeit

Datum: 22.12.2005

Der Verwaltender der Desinfektionsmittel-Kommission im VAH / Desinfektant Commission in VAH — chairman

Beispiel-Platzhalter für die Vorstandschaft der Desinfektionsmittel-Kommission im VAH / example placeholder for the chairman of the Desinfektionsmittel-Kommission im VAH
ENDO STAR (concentrate)

aldehyde free disinfectant

Medical product of the class IIa, CE 0481
Article number 90060 (2-litre bottle), 90061 (5-litre canister), 90062 (150ml bottle)

Type of product:
The product ENDO STAR is a highly effective aldehyde- and phenol-free instrument disinfectant with excellent cleansing qualities. A new, innovative combination of active agents ensures a complete, quick and material caring effectiveness with very low usage concentrations. ENDO STAR is suitable for the reprocessing of all thermostable and thermolable instruments, especially also for anaesthetic accessories, flexible endoscopes and endoscope accessories. Due to the low emission and low formation of foam ENDO STAR is also suitable for the ultra sonic bath (3 % - 5 min).

Tested and released for material compatibility by three leading endoscope manufacturers of the world: Karl Storz (Germany), Richard Wolf (Germany), Pentax (Japan).

Certification by University and Scientific Institutes expert opinions (latest ones):
Bactericidal, fungicidal incl. Aspergillus niger, tuberculocidal incl. M. Terrae, myco-bactericidal according to standard method of the DGHM and EN norms: (prEN 13624, 13727, 14348, 14561, 14562, 14563):
Hygiene Nord GmbH, Greifswald 2004
Standard method of the DGHM:
Prof. Dr. Schubert, Frankfurt 2000
Prof. Dr. Wille, Giessen 2000

Efficacy against covered viruses:
BVDV/ Vaccinia:
Dr. Steinmann, Bremen 2004
Efficiency against HBV/HIV:
Dr. Steinmann, Bremen 2000
Dr. Steinmann, Bremen 2004

Standard method of the DGHM and according to DIN EN 13727, DIN EN 13272, DIN EN 13624 and pr EN 14348:
Hygiene Nord GmbH, Greifswald 2004
M. Terrae efficacy:
Hygiene Nord GmbH, Greifswald 2004

Listed in the disinfection list of the German Society of Hygiene and Microbiology (DGHM)

Dosage and usage: to be diluted in distilled or at least drinking water (best: 20-25°C). Immerse the instruments immediately after use. All surfaces and hollow spaces have to be covered resp. filled. Pay attention to the application concentrations and the working times. Take out the instruments, rinse them thoroughly with water and dry them.

Before the disinfection the instruments have to be cleaned (preferably with the enzymatic cleaner INSTRU ZYM).

1% (10ml) concentrate + 100 % (1 litre) water - effective time 1 hour
2% (20ml) concentrate + 100 % (1 litre) water - effective time 30 min
3% (30ml) concentrate + 100 % (1 litre) water - effective time 15 min
3 % (150ml) concentrate + 100 % (5 litres) water - effective time 15 min

Spectrum of effect:
Bactericidal, fungicidal (incl. Aspergillus niger), tuberculocidal (incl. M-terrae), virus-inactivating (incl. HBV/HIV/Vaccinia, BVDV-HCV)

Main advantages:
+ highly effective with 1, 2 or 3 %; + without emission and smell; + powerful cleaning; + very economical, + excellent material compatibility, + biologically degradable, + good skin tolerance with unintended short-contact.

Active ingredients
100gr contain:
10,0g Quaternary Ammonium Compounds (alkyldimethylammoniumethosulfate)
2,0 g Polyhexamethylenbiguanide,
3,6g Cocospropylendiaminguanidimium-acetat, other ingredients: surfactants, corrosion inhibitors, ph-value regulators.

Chemical and physical data:
Appearance: clear, slightly amber-coloured liquid
Odour: almost none
Density: approx. 1g / cm³
PH-value: 9,5
PH-value of the 1%-usage solution: ca. 8,5

Available Sizes: CE0481
150ml portion bottle, 2-litre bottle and 5-litre canister (other filling units on demand)

Shelf life:
3 years
- for this quantity we offer a 150ml bottle: the user simply pours the contents in a standard tub with 5 litres of water avoiding like this problems and complications with the dosage procedure.

Drinking water can be used for the final rinse if it does not contain pathogen germs, otherwise distilled water. If the water is very hard or if its chloride content is high, we recommend for the final rinse fully desalted water.

For the ultra sonic bath: water temperatures above 45 °C are to be avoided.

The operating and reprocessing instructions of the manufacturers have absolutely to be followed, especially the remarks concerning cleaning, disinfection, rinsing, drying and storage.

The ENDO STAR usage solution does not loose its efficiency in the presence of protein (blood) and can therefore be used several times. When immersing well pre-cleaned instruments the solution can be effective at least until 7 days. However, if the solution becomes turbid it should be changed.

Change of preparation:
ENDO STAR is not compatible with aldehyde based disinfectants. Before the first use and when changing the type of disinfectant the instruments and accessories, the tubs and reprocessing equipments as well as the application aids have to be cleaned and rinsed thoroughly. For a better cleaning before first use we recommend INSTRU SOL.

Storage conditions: do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry

Reuse life:
until 14 days (depends on the degree of soiling)
Deutsche Gesellschaft für Hygiene und Mikrobiologie (DGHM)  
— Desinfektionsmittelkommission —

Zertifikat
über die Aufnahme von

ENDOSTAR

in die Liste der von der DGHM für wirksam befundenen Desinfektionsverfahren.


Hiermit erhält die Firma:
Laboratorium Dr. Doppe
Hoogheweg 35
47906 Kempen

die Bestätigung, daß das Desinfektionsmittel:

ENDOSTAR
Instrumentendesinfektion (einschl. Mycobacterium terrae
gestellt im quantitativen Suspensionssversuch ohne Belastung)
100 g enthalten:
10,0 g Alkyldimethylammoniummethosulfat
2,0 g Polyhexamethylenbiguanid
3,6 g Cocospolyethyldiaminmonosulfamid

aufgrund der vorlegten Gutachten als wirksam erachtet wird.

Für die Anwendung zur Desinfektion in Krankenhäusern und Praxen werden folgende Konzentrationen und Einwirkungszeiten festgelegt:

<table>
<thead>
<tr>
<th>Konzentration</th>
<th>Einwirkungszeit</th>
</tr>
</thead>
<tbody>
<tr>
<td>3,0%</td>
<td>15 min</td>
</tr>
<tr>
<td>2,0%</td>
<td>30 min</td>
</tr>
<tr>
<td>1,0%</td>
<td>60 min</td>
</tr>
</tbody>
</table>

Das Zertifikat verliert 5 Jahre nach Ausstellung seine Gültigkeit.


(Der Vorsitzende der Desinfektionsmittelkommission)
**INSTRU STAR (concentrate)**

(aldehyde- and q.a.c - free disinfectant)

Medical product of the class IIa, CE 0481
Article number 90070 (2-litre bottle), 90071 (5-litre canister)

**Type of product:**
INSTRU STAR is an intensely cleaning, highly effective aldehyde-, phenol- and quaternary ammonium compound free instrument disinfectant on the basis of an innovative, material caring cocodiamine-compound for thermolable and thermostable instruments made of glass, china (porcelain), rubber, metal and plastic. Due to its excellent cleaning qualities INSTRU STAR is most suitable for the reprocessing of surgical and minimal-invasive instruments, as well as of rigid endoscopes (not recommended for flexible endoscopes) and for the use in ultra sonic baths (3% - 5 min). It is also a perfect disinfectant for dental instruments.

Tested and released for material compatibility by two leading endoscopy manufacturers of the world: Karl Storz (Germany) and Richard Wolf (Germany).

Tested according to the standard methods of the DGHM (German Society of Microbiology and Hygiene), the EN-norms for disinfection of instruments and according to the recommendations of the Robert Koch Institute for the efficacy against viruses.

**Certification** by University and Scientific Institutes expert opinions:
Bactericidal, fungicidal, tuberculocidal incl. M. Terrae, myco-bactericidal incl. M.-Avium according to standard method of the DGHM and DIN EN norms:

- (prEN 13624, 13727, 14348, 14561, 14562, 14563):
  - Hygiene Nord GmbH, Greifswald 2003
- Standard method of the DGHM:
  - Prof. Dr. Werner, Schwerin 1996
  - Prof. Dr. Werner, Bischofshofen 2003
  - Prof. Kramer, Greifswald 2003
- Efficacy against Mycobacterium avium:
  - Prof. Werner, Bischofshofen 2003
- According to the DGHM-standard method:
  - Prof. Dr. Schubert, Frankfurt 1995, 1997
  - Prof. Dr. Wille, Giessen 1994
- Efficacy against covered viruses:
  - BVDV (HCV)/ Vaccinia:
    - Dr. Steinmann, Bremen 2004
- Efficiency against HBV/HIV:
  - Dr. Steinmann, Bremen 1997, 2004
  - Prof. Dr. Frösner, München 1997
- Efficiency against MRSA/2200/ATCC 15442:
  - Dr. med H.-M. Seipp, HSK Wiesbaden 1997

Listed in the disinfection list of the German Society of Hygiene and Microbiology (DGHM)

**Dosage and usage:** to be diluted in distilled or at least drinking water (best: 20-25°C) Immense the instruments immediately after use. All surfaces and hollow spaces have to be covered resp. filled. Pay attention to the application concentrations and the working times. Take out the instruments, rinse them thoroughly with water and dry them. Before the disinfection the instruments have to be cleaned (preferably with the enzymatic cleaner INSTRU ZYM).

**Spectrum of effect:**
Bactericidal, fungicidal (incl. Aspergillus niger), tuberculocidal incl. M-terrae, virus-inactivating (incl. HBV/HIV/BVDV-HCV/Vaccinia), myco-bactericidal (incl. M. avium), MRSA.

**Main advantages:**
+ highly effective with 0,5 %, 1 % or 3 %; + without harmful emission and smell; + powerful cleaning; + very economical, + excellent material compatibility, + biologically degradable, + good skin tolerance with unintended short-contact.

**Active ingredients**
100 gr contain:
10,0g Propanol, 22,5g Cocospropylendiammoniumborate, other ingredients: non ionic surfactants, corrosion inhibitors, glycols, perfumes

**Chemical and physical data:**
Appearance: clear, slightly amber coloured liquid
Density: circa 0,98 g / cm3
PH-value: circa 10 (of the concentrate)
PH-value: circa 9 (of the 1%-3% usage solution)

**Available Sizes:**
CE 0481
2-litre bottle and 5-litre canister (other filling units on demand)

**Shelf life:**
3 years

**Reuse life:**
until 14 days (depends on the degree of soiling)
0.25 % (2.5ml) concentrate + 100 % (1 litre) water  effective time 60 min
0.5 % (5ml) concentrate + 100 % (1 litre) water  effective time 30 min
1.0 % (10ml) concentrate + 100 % (1 litre) water  effective time 15 min
3 % (30ml) concentrate + 100 % (1 litre) water  effective time 5 min
Drinking water can be used for the final rinse if it does not contain pathogen germs, otherwise distilled water. If the water is very hard or if its chloride content is high, we recommend for the final rinse fully desalted water.

For ultra sonic bath: water temperatures above 45 °C are to be avoided.

The operating and reprocessing instructions of the manufacturers have absolutely to be followed, especially the remarks concerning cleaning, disinfection, rinsing, drying and storage.

The INSTRU STAR usage solution does not lose its efficiency in the presence of protein (blood) and can therefore be used several times. When immersing well pre-cleaned instruments the solution can be effective at least until 7 days. However, if the solution becomes turbid it should be changed.

Change of preparation:
INSTRU STAR is not compatible with aldehyde containing disinfectants. When you use it for the first time and when you change the preparation all the instruments, accessories, the tubs and the reprocessing equipments and the applications aids have to be thoroughly cleaned and rinsed. For a better cleaning we recommend our cleaner INSTRU SOL FORTE.

Storage conditions: do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry
Zertifikat / Certificate

Über die Konformität der Wirksamkeitsprüfungen für / for conformity of efficacy tests for

Instru Star

mit dem Anforderungskatalog der Deutschen Gesellschaft für Hygiene und Mikrobiologie (DGfM)
- Stand 4.2.2002 - basierend auf den Standardmethoden der DGfM - Stand 1.4.2001 - bzw. den

DGfM und VAH bestätigen die Äquivalenz mit den früher herausgegebenen DGfM-Zertifikaten.

ANTRAGSTELLER / APPLICANT: Laboratorium Dr. Denoe
Hoogheuweg 36
47904 Kempen

WIRKSTOFFE nach Art und Menge bezogen auf 100 ml bzw. 100 g:
Quantities of active substances per 100 ml or 100 g:
22,5 g Coccoenpropyridiammoniumborst

Hiermit wird bestätigt, dass das o.g. Produkt für die prophylaktische Desinfektion in den aufgeführt
Anwendungsbereichen in folgenden Konzentrations-Zeit-Relationen die wirksam eingesetzt wird:
This is to confirm that the above product was found to be effective for prophylactic disinfection in the application
domains listed below at the specified concentration/contact time ratios:

<table>
<thead>
<tr>
<th>Instrumental disinfection for prophylaxis in nursing homes and wards</th>
<th>Instrumental disinfection for prophylaxis in hospital and primary healthcare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organism / Bacteria</td>
<td>Efficacy in min Contact time in min</td>
</tr>
<tr>
<td>geringenempfindliche konditionen</td>
<td>hochempfindliche konditionen</td>
</tr>
<tr>
<td>Mycobacterium avium Asperillus sp.</td>
<td>5                  15              30              60</td>
</tr>
<tr>
<td>Mycobacterium kansas</td>
<td>3,0%&lt;sup&gt;1,3&lt;/sup&gt; 1,0%&lt;sup&gt;1,3&lt;/sup&gt; 0,8%&lt;sup&gt;1,3&lt;/sup&gt; 0,26%&lt;sup&gt;1,3&lt;/sup&gt;</td>
</tr>
<tr>
<td>X</td>
<td>1,0%&lt;sup&gt;1,3&lt;/sup&gt; 0,6%&lt;sup&gt;1,3&lt;/sup&gt; 0,26%&lt;sup&gt;1,3&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Das Zertifikat verfällt 3 Jahre nach Ausstellung seine Gültigkeit / The certificate ceases to be valid 3 years after issue

Bonn, den 11.03.2005

Place/Date

Der Vorsitzende / The Chairman
Desinfektionsmittel-Kommission im VAH / Disinfectant Commission in VAH
Abt. No 11/104
INSTRU STAR R. F. U. (ready-for-use)
aldehyde- and q.a.c. - free disinfectant

Medical product of the class IIa, CE 0481
Article number 90080 (1-litre bottle), 90081 (5-litre canister)

Type of product:
INSTRU STAR r.f.u. is a ready-to-use cleansing liquid with disinfecting effect for rotating instruments sensitive towards corrosion, especially for drills, dental instruments and instruments for the care of the feet. It is suitable also for use in ultra sonic baths.

Aldehyde-, phenol- and quaternary-ammonium-compound-free. Instru Star r.f.u. is the ready-to-use version of Instru Star, modified for the special usage for dental instruments.

Certification by University and Scientific Institutes expert opinions (latest ones):
Standard methods of the DGHM (incl. M. Terrae, M. Avium):
Dr. med. P. Rudolph, Greifswald 2004
Hygiene Nord GmbH, Greifswald 2004
Bactericidal, fungicidal, myco-bactericidal, tuberculocidal:
Hygiene Nord GmbH, Greifswald 2004

Hepatitis B efficacy:
Dr. Steinmann, Bremen 2005

Dosage and usage: immerse instruments after use in undiluted solution. Remove after 15 minutes, rinse and dry well. Do not immerse instruments made of or treated with aluminium, plastic or adhesive!

Storage conditions: do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry

INSTRU STAR R. F. U. (ready-for-use)

Spectrum of effect:
bactericidal, fungicidal, tuberculocidal incl. M.-Terrae, virus inactivating incl. HBV/HIV, myco-bactericidal.

Active ingredients
100 gr contain
1gr Cocospropylenediammoniumborate, corrosion inhibitors, glycol, surfactants, 2-propanol.

Chemical and physical data:
Consistence: Liquid
Odour: specific, nearly odourless
Colour: clear
Density (20°C): 1,1375 - 1,1495 g/ml
PH-value: 10,9 - 12,5
Light refraction (20°C): 1,3725 - 1,3845

Available Sizes: CE 0481
1-litre bottle and 5-litre canister (other filling units on demand)

Shelf life:
3 years

Reuse life:
can be used several times
**INSTRU SUC (concentrate)**

Medical product of the class IIa, CE 0481
Article number 90082 (2-litre bottle), 90083 (5-litre canister), 90084 (10-litre canister)

**Type of product:**
A universal, economical, aldehyde free disinfectant for the highly effective cleansing and disinfection of **sucking equipments in dental areas** with and without amalgam segregation.

**Product properties:**
- bactericidal, fungicidal, virus inactivating (HBV, HIV)
- tuberculocidal
- tested according to the new EN-guidelines EN 13624 and EN 13272 for the disinfection of instruments
- comprehensively and quickly effective
- excellent cleansing properties
- pleasant odour, no contamination of the air
- very good material compatibility
- economical
- foam free

**Usage concentrations:**
At least one time a day after the end of the working day: dilute 20ml (2%) of Instru Suc in 1 litre of water (for each sucking spot) and let the solution suck in through the tubes which have to be cleaned. You can preferably also use warm water until a maximum of 40°C.

**Effective time:** at least 60 minutes or let the solution act over night.
We recommend rinsing (scouring out) the sucking equipment before the application of Instru Suc with clean tap water.
Do not mix Instru Suc with another detergent or cleansing agent.

**Expert opinions:**
Hygiene Nord GmbH, Greifswald, 2004, according to EN 13624 and 13272
For HBV/HIV effectiveness:
Dr. J. Steinmann, Bremen, 2004

**Toxicology:**
Acute toxicity: LD50 > 2000 mg/kg rat. The value has been calculated and is valid for the concentrate. Local toxicity: good skin tolerance of the working solution with short time contact.

**Biological degradability:**
Instru Suc is biologically degradable according to the guidelines of the OECD. The highly diluted usage solution can be disposed of with the normal waste water. With sound practices a disturbance of the biological purification plant is not expected.
According to the EU-guidelines Instru Suc is not to be considered as environmentally damaging.

**Storage conditions:** do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry
INSTRU CARE
instrument oil

Medical product of the class I, CE
Article number 90090 (100ml-bottle), 90091 (400ml aerosol),
90092 (5-litre canister)

Type of product:
Highly pure instrument oil for care, maintenance and protection of medical instruments like surgical, MIC (minimal invasive surgery), orthopaedic and dental instruments and laparoscopes. INSTRU CARE serves for maintaining the functionality and the value of all metal instruments.
Caution with sensitive plastic pieces!
INSTRU CARE lubricates hinges, turbines etc.
INSTRU CARE is physiologically completely harmless, it does not influence the sterilization result, is metal friendly and oxidation resistant until 200°C.

Caution:
Aerosol receptacle is under pressure. Protect from solar radiation and temperatures over 50 °C. Also after use: do not open violently and not burn. Do not spray it against flames or onto glowing objects. Keep away from ignition sources. Do not smoke. Keep away from children. In areas without sufficient airing: developing of explosive mixtures possible.

Application:
INSTRU CARE is used after appropriate cleansing of the instruments and before the sterilization.

Ingredients:
Medical white oils according to the purity requirements of DAB 1996, Pharm. Europ. (PH-EUR. 2 Ed.). BP 1993, USP XXII, NF XVII, FDA Nr. 172-878: 99,9 % Paraffins DAB/USP/BP.
Propellent: propane/butane cosmetic quality according to EU-cosmetic guideline.

Chemical and physical data:
Consistency: Liquid, slightly viscous
Odour: Odourless
Colour: Colourless, clear
Density (20°C): 0.0841 - 0.852 g/ml
PH-value: 10.9 - 12.5
Light refraction° (20 °C): 1.460 - 1.470

Available sizes: CE
400 ml-aerosol can
100 ml-bottle
5-litre canister

Shelf life:
3 years
INSTRU GEL

Medical product of the class I, CE
Article number 90100 (200ml tube)

Type of product:
A perfect medical anti-friction gel based on cellulose for endoscopes, especially fiberscopes and coloscopes. Suitable for all routine examinations (rectal). INSTRU GEL relieves the examination and protects the endoscopes. High anti-frictional effectiveness. Crystal clear, free of fat and water soluble. Relieves the mucous membrane. No anaesthetic, no pharmaceutical product.

Characteristics and advantages:
- highest anti-friction effect through gel forming agent based on cellulose
- creation of a stable, well adhering gliding film for a lasting gliding effect
- unrestricted material compatibility with all usual and current instrument
- free of fats, paraffin, oils, silicon oil
- without additives of pharmacological substances
- completely water soluble and therefore easy to remove
- glass/water-clear
- leaves no residues

For the protection of the sensitive mucous membrane of natural body openings during examinations with endoscopes it is indispensable to apply a preparation which creates an anti-friction-film. INSTRU GEL is suitable for the application of all usual endoscope instruments for examinations at natural body openings up to 1 hour.

To be observed:
INSTRU GEL contains as preservatives parabens. Possible hypersensitivity / allergy towards parabens are to be excluded before the examination.

Composition:
INSTRU GEL contains gel forming agents based on cellulose for the creation of aqueous gliding gels, glycerine as natural humidifier for a long lasting anti-friction effect, lactic acid as ph-regulator, parabens preservatives as secure protection against microbial contamination.

Storage conditions: do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry
ENODMAT PLUS (concentrate) aldehyde based
Instrument disinfectant for the chemo-thermal reprocessing in washing machines

Medical product of the class IIa, CE 0481
Article number 90170 (5-litre canister)

Type of product:
ENDOMAT PLUS and LABOMAT E are to be used in combination and are a system for the chemical-thermal reprocessing of rigid and flexible endoscopes and accessories between 50°C and 60°C. ENDOMAT PLUS cleanses and disinfects very thoroughly and completely and without formation of foam in fully automatic reprocessing washer disinfectors, so called ECD-automates. Suitable for all commonly used washer disinfectors on the world market (including Olympus machines of course), well tolerated on material, foam stable.

Tested and released for material compatibility by three leading endoscope manufacturers of the world: Karl Storz (Germany), Richard Wolf (Germany), Pentax (Japan).

Complies with the DKHG recommendation: with RF > 10 log steps to the reprocessing procedure. - Tested by independent expert opinions according to the EN-norm 15883 for the disinfection of instruments and according to the recommendations of the Robert Koch Institute for the efficacy against viruses

Expert opinions:
Bactericidal, fungicidal
Prof. Dr. med. R. Schubert, Frankfurt, 2001, 2002

According to the guidelines of the DGHM:
Prof. Dr. med. R. Schubert, Frankfurt 2005

HBV/HIV:
Dr. J. Steinmann, Bremen, 2001
Papovavirus SV 40, Vaccinia, BVDV/HCV, Adeno:
Dr. J. Steinmann, Bremen 2002
Polio:
Dr. J. Steinmann, Bremen 2005

Expert opinion according to prEN ISO 15883:
Institut für angewandte Hygiene, Graz 2006

Expert opinion about the disinfecting and cleansing properties on Fujinon endoscopes:
(bronchoscope BRO Y3S, gastroscope UGI FP2, UGI F4, colonoscope COL LT)
Prof. Dr. Werner, Mainz 1990

Chemical-thermic reprocessing:
The mechanical cleansing is carried out with the enzymatic detergent Labomat E. The mechanical disinfection is carried out with the disinfectant Endomat Plus. The dosages are carried out by the dosing pumps of the RDG-E washer machine systems.

For the cleansing step we recommend a temperature between 35°C and 40°C. Higher temperatures can cause coagulations. Temperatures of the intake water clearly below 35°C can cause the formation of foam. Labomat E and Endomat Plus are fitted with lime inhibitors in order to prevent depositions of lime in the washing chambers and on the endoscopes. It is recommendable to make the final rinse with fully desalted water. The instructions of the machine manufacturers for the installation and maintenance have to be followed. Ion exchanger are to be regenerated in due time.

Spectrum of effect:
bactericidal, mycobactericidal, fungicidal, tuberculocidal (incl. M. terrae) and virus inactivating incl. HBV/HIV (1% - 5 min), Adeno (1% - 5 min), BVDV/HCV (1% - 5 min), Polio (1% - 5 min), Vaccinia (1% - 5 min), Papovavirus SV 40 (1% - 5 min), DHBV-effective.

Active ingredients in 100 ml:
5,25g Formacetale
3,50g Glyoxal
4,25g Glutardialdehyde
1,90g Quaternary ammonium compounds

Chemical-physical data:
Appearance: slightly yellowish, clear
Density 20°C: 1,036  g/cm³
Ph-value: circa 5
Refractive index 20°C: 1,365 - 1,375

Available sizes: CE 0481
5 litre canister

Shelf life:
3 years

Storage conditions:
do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry

Manual Pre-Cleansing:
see Labomat E

Application:
The dosage is carried out automatically by the dosing pump of the machine.

Pre-cleansing:
Labomat E: 0,5%
Disinfection:
Endomat Plus: 1,0 % - 5 minutes

(Please pay attention to the indications of the corresponding machine manufacturer)
LABOMAT E (concentrate) enzymatic detergent
Enzymatc cleansing liquid for endoscope washer machines
(in combination with Endomat Plus)

Medical product of the class I, CE
Article number 90120 (5 litre canister)

Type of product:
LABOMAT E is a cleansing concentrate working on the basis of enzymes for cleaning and/or pre-cleaning of medical instruments in re-processing machines (chemical/thermal procedure).
It has been specially developed for the use for endoscopes.
It has a neutral ph-setting and represents a specially adjusted cleansing system with highly active enzymes. Due to its composition LABOMAT E is very well biologically degradable. Suitable for all washer machines.

Product properties:
- cleanses thoroughly and material caring
- very economical
- biologically well degradable
- high capability of dissolving blood
- complies with the recommendation of the DKHG for the cleansing with RF 4 log-steps (pre-rinsing + cleansing) and is tested according to the EN norm 15883

Expert opinions:
About the cleansing properties on flexible endoscopes:
Institut für angewandte Hygiene, Graz 2006

About the chemical-thermic disinfection in combination with Endomat Plus:
Prof. Dr. med. Schubert, Frankfurt 2001

„Efficacy of 10 different cleaning processes in a washer-disinfector for flexible endoscopes“ Charité-University-Medical-Science, Campus Benjamin Franklin, Berlin - 2005

Labomat E was tested along with 9 other comparable detergents and was among those with excellent results (3 other detergents from well known manufacturers however were discarded: No significant difference between use of water alone and the cleaning process was found with three cleaning processes: …)

Manual Pre-Cleansing:
According to the degree of dirt a pre-cleansing step has to be carried out taking into account the recommendations of the endoscope manufacturers. Only suitable detergents are to be used. We recommend the enzymatic cleaner Instru Zym. For a cleansing disinfection aldehyde-containing products like Instru Plus are to be preferred.
If aldehyde free preparations are used for this reprocessing step, like for example Endo Star, the endoscopes have to be thoroughly rinsed with water before the mechanical reprocessing.

Usage instructions for LABOMAT E for re-processing machines:
LABOMAT E is used as a 0,5 % usage solution.
The re-processing temperature should be between 35° and 40° C.
The usage concentration is adjusted automatically by the dosing pumps of the used re-processing equipment.
The following water qualities are recommended: drinking water quality for the usage solution. A final rinsing after a completed re-processing procedure should be carried out with demineralised water.

The operating instructions, working programmes and adjustments of the re-processing machines have to be observed according to the specifications of the machine manufacturers.
LABOMAT SPM (concentrate)
Neutral enzymatic cleansing liquid for washer machines

Medical product of the class I, CE
Article number 90130 (5 litre canister)

Type of product:
LABOMAT SPM was developed for the thermo-chemical mechanical re-processing of all surgical instruments and anaesthesia equipment, especially for fine lumen instruments, such as laparoscopes, MiC- (minimal invasive) and orthopaedic instruments. Proteases ensure a powerful cleaning of substances such as albumin, blood and secretory products. Amylases ensure that bio-films can not build up. Well tolerated on material.

Usage instructions for Labomat SPM for re-processing machines:
LABOMAT SPM is applied as a 0.5 % usage solution.
The re-processing temperature should be between 35 °C and 40 °C.

For the ultra sonic bath: dosage 1 - 3 %, temperature up to 40°C.

The usage concentration is adjusted automatically by the dosing pumps of the working re-processing equipment.

The following water qualities are recommended: drinking water for the usage solution.
A final rinsing after a completed re-processing procedure should be carried out with demineralised water.

The operating instructions, working programmes and adjustments of the re-processing machines have to be observed according to the specifications of the machine manufacturers.

Storage conditions: do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry

Ingredients:
Enzymes, non ionic surfactants, alcohols, corrosion inhibitors, preservatives, auxiliary agents.

Available sizes: CE
5 litre canister

Chemical-physical data:
Appearance: liquid
Odour: specific, weak
Colour: colourless or slightly yellowish
Density 20°C: 1.0380 - 1.0490 g/cm³
Ph-value (18 - 28°C): 5.6 - 5.8
Light refraction °20°C: 1.3740 - 1.3840

Shelf life:
2 years
LABOMAT MA LIQUID (concentrate)
Mild alkaline liquid cleaner

Cleansing product
Article number 90150 (5 litre canister)

Type of product:
LABOMAT MA LIQUID is a mild alkaline cleaner based on amphosurfactants for the mechanical re-processing of surgical, dental and medical instruments as well as anaesthesia equipment, surgeon’s shoes and laboratory equipment. Good cleaning effect; removes all organic contaminants. Well tolerated on material; suitable for MIC-instruments and laparoscopes. Creates no foam. Phosphate and silicate-free. Works at water temperatures from 40°C to 93°C. Biologically degradable.

Application area:
Thermo alkaline cleansing at 93°C and chemical thermal at 60°C.

Usage instructions for Labomat Ma Liquid for re-processing machines:
LABOMAT MA LIQUID is used as a 0.3% usage solution (3 ml / 1 l water).

The usage concentration is adjusted by the dosing pumps of the used re-processing equipment.

The following water qualities are recommended: drinking water quality for the usage solution. A final rinsing after a completed re-processing procedure should be carried out with demineralised water.

The operating instructions, working programmes and adjustments of the re-processing machines have to be observed according to the specifications of the machine manufacturers.

Storage conditions: do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry

Ingredients:
Soda, complex constituting agent, sodium silicates, non ionic surfactants, corrosion inhibitors, auxiliary agents

Chemical-physical data:
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Odour</td>
<td>weak pharmaceutics like</td>
</tr>
<tr>
<td>Colour</td>
<td>colourless</td>
</tr>
<tr>
<td>Density 20°C</td>
<td>1.0500 - 1.0650 g/cm³</td>
</tr>
<tr>
<td>Ph-value (18 - 28°C)</td>
<td>12.5 - 13.6</td>
</tr>
<tr>
<td>Light refraction 20°C</td>
<td>1.3530 - 1.3630</td>
</tr>
</tbody>
</table>

Available sizes:
5 litre canister

Shelf life:
2 years
LABOMAT KS (concentrate)
Material caring rinsing agent

Cleansing product
Article number 90160 (5 litre canister)

Type of product:
LABOMAT KS is a mild rinsing (neutralization) agent based on natural organic acids (citric acids). Phosphate- and surfactant-free. Non toxic. **Ensures a quick, stainless drying.** Toxicologically harmless. Dissolves also limestone residues.

- Environmental friendly rising fluid with shining effect
- Toxicologically harmless

Application area:
For the neutralization after the use of an alkaline liquid cleaner (LABOMAT MA LIQUID) in anaesthetic washing machines

The dosage is being carried out automatically by the dosing pump of the machine.
Adjustment: 0,1 - 0,5 %

Storage conditions: do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry

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**Chemical-physical data:**
- Appearance: liquid
- Odour: specific
- Colour: colourless, clear
- Density 20°C: 1,1129 - 1,1249 g/cm³
- Ph-value (18 - 28°C): 1,0 - 2,3
- Light refraction °20°C: 1,3645 - 1,3745

**Available sizes:**
5 litre canister

**Shelf life:**
2 years
Alcoholic rapid spray disinfectant

Medical product of the class IIa, CE 0481
Article number 90181 (200ml bottle), 90182 (1 litre bottle), 90183 (5 litre canister)

Type of product:
Alcoholic rapid disinfectant based on various alcohols and a new bispyrididamin derivate. For all areas with risk of infection and use in the proximity of patients. Highly effective and extremely quick ready-to-use disinfectant for immediate use in all clinical areas, laboratories, surgeries, dental areas, ambulances for alcohol resistant surfaces and instruments. Perfect in-between surgical treatment and examinations when extremely short contact times are necessary (2,5 - 5 minutes).

Certification by University and Scientific Institutes expert opinions:
Bactericidal, fungicidal, tuberculocidal, incl. M-Terrae:
Prof. Dr. med. J. Beckert, Lübeck, 1991
Prof. Dr. med. B. Wille, Giessen, 1993
HBV/HIV- effectiveness:
Prof. Dr. med G. Frösner, München, 1992
Instrument disinfection:
Prof. Dr. Wille, Giessen, 1994
Hygiene Nord Gmbh, Greifswald, 2004
BVDV/HCV, Vaccinia efficacy (30 sec.):
Dr. J. Steimann, Bremen 2004

Listed in the disinfection list of the German Society of Hygiene and Microbiology (DGHM)

Chemical-physical data:
- Appearance: clear, colourless liquid
- Density 20°C : 0,9190 - 0,9290 g/cm3
- Ph-value at 20°C : circa 6,5 - 7
- Refractive index 20°C: 1,367 - 1,369
- Flash point (DIN 51755): 25°C

Dosage/Usage:
Surfaces and instruments must be completely moistened. Effective time 5 min.

Note: do not exceed an output of max 50ml per square meter. Be careful with materials which are sensitive to alcohols and with alcohol-dissoluble paint coats and varnishes.

Also available in 25ml spray bottle for rapid disinfection of lavatories/toilets (during journey)

Storage conditions: do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry

Available Sizes: CE 0481
200 ml-spray-bottle; 1-litre. 2-litre bottle and 5-litre and 10-litre canister (other filling units on demand)

Spectrum of effect:
Bactericidal (incl. Mycobacterium avium), fungicidal (incl. Aspergillus niger), tuberculocidal (incl. M-terrae), virus-inactivating (incl. HBV/HIV, BVDV/HCV, Vaccinia), MRSA.

Main advantages:
+ highly effective; + quickness; + pleasant smell; + gentle on instruments; + low alcohol contents; + aldehyde free; + good skin tolerance with short contact + for plastic surfaces.

Active ingredients
- 100 gr contain:
  27.5g 2-propanol,
  11.9g ethanol,
  0,05g bispyrimidin-aminderivate; additional substances: wetting agent, aromatics, auxiliary agents.

Shelf life: 3 years
Zertifikat / Certificate

Spray in


DGHM und VAH bestätigen die Anwendung mit den Gültigkeitsbereichen DGHM-Zertifikat, with the Requirements issued by the German Society for Hygiene and Microbiology (DGHM) on February 4, 2002 which is based on the DGHM Standard Methods of September 1, 2001 or the transitional provisions of Sept. 4, 2002. DGHM and VAH confirm the use with the valid DGHM issued DGHM certificates.

ANTRAGSTELLER / APPLICANT: Laboratorium Dr. Epple
Hauptstrasse 35
47805 Krefeld

WIRKSTOFFE nach Art und Menge bezogen auf 100 ml bzw. 100 g

<table>
<thead>
<tr>
<th>Quantity of active substances per 100 ml or 100 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>27,6 g 2-Propanol</td>
</tr>
<tr>
<td>11,6 g ethanol</td>
</tr>
<tr>
<td>0,05 g Chloramphenicol</td>
</tr>
</tbody>
</table>

Hiermit wird bestätigt, dass das o.g. Produkt für die prophylaktische Desinfektion in den aufgeführten Anwendungsbereichen in folgenden Konzentrationen als wirksam eingestuft wird:

This is to confirm that the above product was found to be effective for prophylactic disinfection in the application
described below at the specified concentration contact time ratio:

<table>
<thead>
<tr>
<th>Resistance to Human Pathogens in Mammals and Prions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zuätzlich eingeschränkt gegen (aerob)lytische active gegen (aerob)lytische active gegen</td>
</tr>
<tr>
<td>Mycobacterium leprae, Mycobacterium avium, A. niger, Trichophyton mentagrophytes, P. auf roten Stäbchen auf roten Stäbchen</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wachsen</th>
<th>Chemotherapeutische</th>
<th>Einwirkzeit in min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistenz</td>
<td>Reaktionsfähigkeit</td>
<td>240</td>
</tr>
<tr>
<td>neutra</td>
<td>neutral</td>
<td>36</td>
</tr>
</tbody>
</table>

Das Zertifikat verfällt 3 Jahre nach Aushändigung des Gültigkeit / The certificate expires in 3 years after issue

Ben.: am 28.01.2005

Place/Date

Der Vertretende der / The Chairman of the
Desinfektionsmittel-Kommission im VAH / Disinfectant Commission in VAH
SPRAY OFF N (ready-to-use)

Alcoholic rapid spray disinfectant in 30 sec.

Medical product of the class IIa, CE 0481
Article number 90194 (1 litre bottle), 90195 (5 litre canister)

Tested according to the standard methods of the DGHM (German Society of Microbiology and Hygiene) for the disinfection of surfaces and according to the recommendations of the Federal Robert Koch Institute for the efficacy against viruses

Type of preparation:
SPRAY OFF N is a ready-to-use, very quickly effective preparation for the cleansing and disinfection of alcohol resistant surfaces of medical devices and equipments including medical instruments. SPRAY OFF N is especially suitable for application in the presence of patients where short impact times are required between treatments and operations.

Expert opinions:
For the disinfection of surfaces according to the standard methods of the DGHM:
Prof. med. R. Schubert, Frankfurt 2001
Prof. med. W. Solbach, Lübeck 2001
Prof. med. R. Schubert, Frankfurt 2003
Efficiency against HBV (HIV):
Dr. Steinmann, Bremen 2000
Efficiency against BVDV (HCV), Vaccinia:
Dr. Steinmann, Bremen 2004
M.- terrae efficacy:
Hygiene Nord GmbH, Greifswald 2004

Listed in the disinfection list of the German Society of Hygiene and Microbiology (DGHM)

Application areas:
For all alcohol resistant surfaces and objects, especially for surfaces of equipments and objects in the area near to the patient in clinics, doctors’ practices, nursing and old people’s homes, ambulances, kitchen- and food processing areas.

Usage:
SPRAY OFF N is ready-to-use. Wet completely the surfaces and objects which are to be disinfected with SPRAY OFF N.

To be observed:
Maximum application 50 ml/m². Be cautious with alcohol sensitive materials and alcohol soluble varnishes/paint coats.

Storage conditions: do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry

Spectrum of effect:
Bactericidal, fungicidal, tuberculocidal (incl. M-terrae), virus-inactivating (incl. HBV/HIV, BVDV/HCV, Vaccinia), MRSA.

Main advantages:
+ highly effective (30 sec); + quickness; + pleasant smell; + gentle on instruments; + low alcohol contents; + aldehyde free; + good skin tolerance with short contact; + for plastic surfaces.

Chemical and physical data:

| Appearance of the concentrate: Clear, colourless liquid |
| PH-value: ca. 6,5 - 7 |
| Density 20°C: ,880 - 0,900 g/cm³ |
| Refractive index: D20 = 1,3624 - 1,3654 |

Composition (100 g contain):
30 g 1-Propanol
15 g 2-Propanol
10 g Ethanol
0,05 g Didecylmethylammoniumpropionat
0,02 g Alkylaminguandindiacetat
Other ingredients: perfumes, wetting agents

Available Sizes: CE0481
1 litre bottle
5 litre canister
10 litre canister

Shelf life:
3 years
**Zertifikat / Certificate**

über die Konformität der Wirksamkeitsprüfungen für / conformity of efficacy tests for


DGHM und VAH bestätigen die Äquivalenz mit den früher herausgegebenen DGHM-Zertifikaten with the Requirements catalogue of the German Society for Hygiene and Microbiology (DGHM) on February 4, 2002 which is based on the DGHM Standard Methods of September 1, 2001 or the transitional regulations of September 4, 2002. DGHM and VAH confirm the equivalence to the former issued DGHM certificates.

**ANTRAGSSTELLE / APPLICANT:**
Laboratorium Dr. Jappe
Hoogheweg 35
47906 Kempen

**Vermittelt durch**

**Zweckzweck**

Hiermit wird bestätigt, dass das angeforderte Produkt für die prophylaktische Desinfektion in den aufgeführten Anwendungsgebieten durch die genannten Konzentrations-Zeit-Relationen als wirksam eingestuft wird.

This is to confirm that the product was found to be effective for prophylactic disinfection in the application domains listed below at the specified concentration/contact time ratios:

<table>
<thead>
<tr>
<th>Mechanism of Action</th>
<th>Organic Loading</th>
<th>Incubation</th>
<th>Contact Time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylene blue</td>
<td>Gram-positive</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Gram-negative</td>
<td>15</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>Yeasts</td>
<td>15</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td>Viruses</td>
<td>15</td>
<td>240</td>
</tr>
</tbody>
</table>

**Verantwortlicher**

**Gerätetyp**

- Desinfektionsmittel-Kommission im VAH -
- Disinfectant Commission in VAH

**Unterschriften**

Ermn. am 22.12.2005
Place/Date

Der Vorsitzende der 
The Chairman of the
Desinfektionsmittel-Kommission im VAH -
Disinfectant Commission in VAH -

Deutschland / Germany
TOP OFF wipes
aldehyde free

Medical product of the class IIa, CE 0481
Article number 90200 (150 wipes box), 90201 (150 refill-package)

**Type of product:**
Hygienic ready-to-use wipes (soaked with SPRAY OFF N) for the cleaning and disinfection of all alcohol resistant surfaces and equipments, also in the proximity of patients. They are very economical due to the use of re-fill-boxes. The wipes are lint-free, not sticky, do not dry up and leave no visible residue. They are perfect for small surfaces and small equipments.

The unfolded size of each wipe is 13.5 x 20 cm.

**Note:** Be careful with materials which are sensitive to alcohols and with alcohol-dissoluble paint coats and varnishes.

**Storage conditions:** do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry.

**Ingredients and spectrum of effect:**
Main advantages:
- highly effective;
- quickness;
- pleasant smell;
- gentle on instruments;
- low alcohol contents;
- aldehyde free;
- good skin tolerance with short contact;
- lint free.

**Available sizes:**
- 150 wipes box
- 150 wipes re-fill-package

**Shelf life:**
3 years
Medical product of the class IIa, CE 0481
Article number 90210 (2-litre bottle), 90211 (5-litre canister),
90212 (10-litre canister)

Type of product:
ACETAL COMBI is a universal surface disinfectant and combined cleaning liquid based on a special acetal formulation in combination with quaternary ammonium compounds. It is suitable for areas of work place hygiene as well as for all medical areas where high dirt and odour stress occurs. It is perfectly suitable for the routine disinfection of all water resistant surfaces and has an excellent cleaning power. It is for wiping surfaces and also for immersing objects and for the disinfection of urinals. It eliminates odours, has a pleasant smell and is well tolerated on materials. Highly effective even at 0,5%.

• suitable for central and peripheral dosing equipments
• suitable for urinals, tubs and washer machines
• suitable for mixing systems in tub equipments
• suitable for combat against athlete’s foot/dermatophyte
• suitable for disinfection of objects by immersing them

Certification by University and Scientific Institutes expert opinions:
Prof. Dr. Lamers, Dortmund, 1986
Prof. Dr. Drösner, München, 1994
Hygiene Nord GmbH, Greifswald, 2004
Prof. Kramer, Greifswald, 2004

Listed in the disinfection list of the German Society of Hygiene and Microbiology (DGHM)

Dosage concentration:
According to DGHM:
0,5 % (5ml) concentrate + 100 % (1 litre) water - effective time 4 hours
1 % (10ml) concentrate + 100 % (1 litre) water - effective time 1 hour
2 % (20ml) concentrate + 100 % (1 litre) water - effective time 30 min
3 % (30ml) concentrate + 100 % (1 litre) water - effective time 15 min

Storage conditions: do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry

Spectrum of effect:
bactericidal, fungicidal, tuberculocidal incl. M. terrae, virucidal (HBV, HIV: 2 % - 15 min), (HCV, Vaccinia: 1 % - 15 min), Avian Flu virus, Aspergillus niger, (Polio, Adeno, SV 40, Parvo: 3 % - 120min)

Active ingredients - 100 g. contain:
5,25 g Formacetale
2,80 g Formaldehyde
2,80 g Glyoxale
1,75 g Glutaraldehyde
3,50 g Benzalconiumchloride

Chemical and physical data:
Appearance of the concentrate: clear, light green liquid
PH-value at (20 °C): 5,0 6,0
Density at 20 °C: 1,0385 1,0485 g / cm³
Refractive index: n 20= 1,363 1,371
PH-value of the 1% solution in drinking water: circa 7

Available sizes: CE 0481
2 litre bottle, 5 litre canister, 10 litre canister

Shelf life:
3 years
ALPHA GUARD (concentrate)

Medical product of the class IIa, CE 0481
Article number 90220 (2-litre bottle), 90221 (5-litre canister), 90222 (10-litre canister)

Type of product:
ALPHA GUARD is a universal, aldehyde- and phenol-free disinfectant and cleansing liquid based on biguanide and quaternary ammonium compounds for all water- and wipe resistant surfaces in medical facilities, also in food-preparation-process areas (kitchen et cetera incl. refrigerators and even for dishes and cutlery) and in the infant and new born area of hospitals, including incubators. It is also suitable for immersing objects. It is extremely high concentrated and has a powerful cleaning effect, a pleasant smell, no emission, is well tolerated on material and skin friendly.
It can also be applied for the disinfection of incubators.

Certification by University and Scientific Institutes expert opinions:
For the disinfection of surfaces according to the standard methods of the DGHM:
Hygiene Nord GmbH, Greifswald 2004
Prof. Dr. Wille, Giessen 1995
Prof. Dr. Schubert, Frankfurt 1994
Efficiency against Tbc (M. terrae):
Prof. Dr. Schubert, Frankfurt 1999
Efficiency against HBV (HIV):
Dr. Steinmann, Bremen 1990
Efficiency against BVDV (HCV)
Dr. Steinmann, Bremen 2004
Efficiency against Vaccinia:
Dr. Steinmann, Bremen 2004

Listed in the disinfection list of the German Society of Hygiene and Microbiology (DGHM)

Dosage concentration according to DGHM:
0,25 % (2,5 ml) concentrate + 100 % (1 litre) water effective time 4 hours
0,50 % (5ml) concentrate + 100 % (1 litre) water effective time 1 hour
1,00 % (10ml) concentrate + 100 % (1 litre) water effective time 30 min
1,50 % (15ml) concentrate + 100 % (1 litre) water effective time 15 min

For dishes and cutlery 0,25 %.
Quick disinfection: 8 % - 1 min

Storage conditions: do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry
Verbund für Angewandte Hygiene (VAH)
Association for Applied Hygiene

Deutsche Gesellschaft für Hygiene und Mikrobiologie (DGHM)
German Society for Hygiene and Microbiology

– Desinfektionsmittel-Kommission im VAH –
Disinfectant Commission in VAH

Zertifikat / Certificate
über die Konformität der Wirksamkeitsprüfungen für / for conformity of efficacy tests for

Alpha Guard

mit dem Anforderungskatalog der Deutschen Gesellschaft für Hygiene und Mikrobiologie (DGHM)

DGHM und VAH bestätigen die Äquivalenz mit dem früher herausgegebenen DGHM-Zertifikat.

LGIM und VAG bestätigen die Äquivalenz mit dem früher herausgegebenen DGHM-Zertifikat with the Requirements issued by the German Society for Hygiene and Microbiology (DGHM) on February 4th 2002 which is based on the DGHM Standard Methods of September 1st 2001 or the transitional provisions of Sept. 4th 2002. DGHM and VAH confirm the equivalence of the former issued DGHM certificates.

ANTRAGSTELLER / APPLICANT: Laboratorium Dr. Depe
Hoogtoren 33
47906 Kempen

WIRKSTOFFE nach Art und Menge bezogen auf 100 ml bzw. 100 g:
Quantity of active substances per 100 ml or 100 g:

8.6 g Didecyldimethylammoniumchlorid
2.5 g Polyhexamethylenbiguanidhydrochlorid

Hiermit wird bestätigt, dass das o.g. Produkt für die prophylaktische Desinfektion in den aufgeführtren Anwendungsbereichen in folgenden Konzentrations-Zeit-Relationen als wirksam eingesetzt wird:
This is to confirm that the above product was found to be effective for prophylactic disinfection in the application domains listed below at the specified concentration contact time ratios:

<table>
<thead>
<tr>
<th>Flächendesinfektion zur Prophylaxe in Krankenhäuser und Praxis</th>
<th>Surface disinfection for prophylaxis in hospital and primary healthcare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zusätzlich wirksam gegen: Additionally active against:</td>
<td></td>
</tr>
</tbody>
</table>
Mycobacterium terrae, Mycobacterium avium, Aspergillus niger | Tchophyton mentagrophytes (Plaue auf rohem Holzbünden an untreated wood) |

<table>
<thead>
<tr>
<th>Method</th>
<th>Mechanical action</th>
<th>Organische Belastung</th>
<th>Einwirkzeit in min</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ohne/without</td>
<td>gering/dilute</td>
<td>hoch/dilute</td>
</tr>
<tr>
<td>mittel</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>15</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1,5%</td>
<td>1,0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0,50%</td>
<td>0,25%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>240</td>
<td></td>
</tr>
</tbody>
</table>

Das Zertifikat verfällt 3 Jahre nach Ausstellung seiner Gültigkeit. The certificate expires to be valid 3 years after issue.

Bonn, den 28.01.2005
Place/Date

Der Vorsitzende der Desinfektionsmittel-Kommission im VAH
The Chairman of the Desinfectant Commission in VAH
BETA GUARD  (concentrate)
aldehyde free

Medical product of the class IIa, CE 0481
Article number 90230 (2-litre bottle), 90231 (5-litre canister),
90232 (10-litre canister)

Type of product:
BETA GUARD is an aldehyde- and phenol-free surface disinfectant based
on a new quaternary ammonium combination with excellent cleansing characteristics. For all water- and wipe-resistant surfaces and for immersing ob-
jects. Ideal for areas with high degree of soiling and odour. Suitable also for kitchen and food-processing areas. For all dosing equipments. Good material to-
lerance. Economical through low dosage concentrations.

Certification by University and Scientific Institutes expert opinions:
For the disinfection of surfaces according to the standard methods of the
DGHM:
Hygiene Nord GmbH, Greifswald 2004
Prof. Dr. Schubert, Frankfurt 1994
Prof. Dr. Wille, Giessen 2004
Surface disinfection according to DVG:
Dr. Färber, Giessen 1994
M.-Terrae-efficacy:
Prof. Dr. Schubert, Frankfurt 1999
HBV-/HIV-efficacy:
Dr. Steinmann, Bremen 2000
According to the DGHM standards:
Prof. Dr. med. Burkhard Wille, Giessen 2000
BVDV (HCV)/ Vaccinia-efficacy:
Dr. Steinmann, Bremen 2004
Feline Calicivirus (FCV) - efficacy:
Dr. Steinmann, Bremen 2004

Listed in the disinfection list of the German Society of Hygiene and Microbiology
(DGHM)

Dosage concentration according to DGHM:
Bactericidal, fungicidal:
0,5 %  (5ml) concentrate + 100 % (1 litre) water - effective time 4 hours
1 %  (10ml) concentrate + 100 % (1 litre) water - effective time 1 hour
3 %  (30ml) concentrate + 100 % (1 litre) water - effective time 15 min

Virus inactivating, incl. HBV/HIV:
1 % (10ml) concentrate + 100 % (1 litre) water - effective time 30 min
3 % (30ml) concentrate + 100 % (1 litre) water - effective time 5 min

For disinfection of linen: 5 % - 2 hours (immerse the linen in a tub)

Storage conditions:  do not allow temperatures below 0 °C or above 30 °C; do
the product not expose to direct sunlight; keep the store dry

Spectrum of effect:
bactericidal, fungicidal, tuberculocidal (incl.
M. Terrae), virus-inactivating (incl. HBV,
HIV, BVDV-HCV, Vaccinia, Avian Flu virus).

Active ingredients - 100 qr contain:
5g Didecyldimethylammoniumchlorid
Other components: ph-value regulators, aux-
iliary, solvent and perfume agents

Chemical and physical data:
PH-value: ca. 8,8 - 9,5
Density 20°C: 0,9963 g/cm³
PH-value of the 0,5%-usage soluti-
ion in tap water: circa 8
Refractive index
20°C: 1,3575 - 1,3775

Available sizes: CE 0481
2 litre bottle,
5 litre canister,
10 litre canister

Shelf life:
3 years

Surfaces
Surfaces cleansing and disinfection

BETA GUARD Surfaces cleansing and disinfection aldehyde free

Spectrum of effect:
Bactericidal, fungicidal, tuberculocidal (incl. M. Terrae), virus-inactivating (incl. HBV, HIV, BVDV-HCV, Vaccinia, Avian Flu virus).

Active ingredients - 100 qr contain:
5g Didecyldimethylammoniumchlorid
Other components: pH-value regulators, auxiliary, solvent and perfume agents

Chemical and physical data:
PH-value: ca. 8.8 - 9.5
Density 20°C: 0.9963 g/cm³
PH-value of the 0.5%-usage solution in tap water: circa 8
Refractive index
20°C: 1.3575 - 1.3775

Available sizes: CE 0481
2 litre bottle,
5 litre canister,
10 litre canister

Shelf life:
3 years
HANDS AND SKIN

**Hand hygiene:**
Most germs are transmitted through the hands. Hand hygiene is therefore a very important factor for avoiding the transmission of diseases.

**Hand washing:**
Hand washing removes dirt by rinsing. Intensive hand washing reduces the quantity of germs, but does not destroy them.

**Hygienic disinfecting hand washing:**
This procedure reduces germs better than 1 minute of ordinary hand washing. It is used in areas that require higher than normal hygienic standards such as food processing facilities. The products are tested according to EN 1499. This method however does not comply with the clinical standards of hygienic hand disinfection.

**Hygienic hand disinfection:**
This procedure reduces germs that are created on transient flora due to contamination. Products are tested according to EN 1500.

**Surgical hand disinfection:**
This procedure additionally destroys germs that generally exist on the skin. Products are tested according to EN 1291.

**Hand protection and hand/skin care:**
The protective function of the skin is decreased if hands have stressed/damaged skin or fissures. Impaired skin is difficult to disinfect. Therefore daily hand care before, during and after work has great importance.

**An effective skin-care**
- reduces germs to prevent from infection
- supports the blood circulation to regenerate the skin
- maintains the protective mechanism of the skin
- reduces skin damages and decubitus

Frequent washing due to soiling and regular disinfection as a result of contamination stresses the hands of the nurses in addition. These hands need daily protection to keep the pH-value of the skin stable and to prevent from skin damages.
LOTIO LIND
Skin care lotion

Cosmetic product
Article number 90300 (200ml tube), 90301 (500ml bottle)

**Type of product:**
A high quality oil-in-water emulsion with skin friendly emulsifying agents. For all personnel and staff for the regular care of stressed skin and especially hands in all medical areas. Fat- and silicone-free. Is rapidly absorbed by the skin. Ideal for hand care during breaks (in-between-times). Also most suitable for the every-day-use of just everybody.

**Storage conditions:** do not allow temperatures below 0 °C or above 30 °C; do not expose to direct sunlight; keep the store dry

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**Active agents:**
bisabolol.
vitamin E + A and panthenol.

**Ingredients:**
aqua, caprylic/capric triglyceride, cetearyl alcohol, ceteareth-25, paraffinum liquidum, isopropylmyristate, ceteareth-6, tocopheryl acetate, bisabolol, retinyl palmitate, arachis hypogaea, panthenol, propylparaben, methylparaben, ethylparaben, phenoxyethanol, perfume.

**Chemical and physical data:**
- Consistence: liquid, emulsion
- Odour: slightly perfumed
- Colour: white
- Density 20°C: 0.980 - 0.990 g/cm³
- PH-value: 5.5 - 6.7

**Available sizes:**
- 200 ml tube
- 500 ml bottle

**Shelf life:**
3 years
LOTIO C PLUS
Skin care cream

Cosmetic product
Article number 90310 (75ml tube)

* special protection of the skin for the clinic and the doctor’s practice

**Type of preparation:**
LOTIO C PLUS is an innovative, actively substances separating preparation, which protects effectively from skin damages caused by workplace conditions; it protects especially from aggressive chemicals, acids, powders, allergen substances and contact allergies.

**Product properties:**
- Special active substances like stearates and polymers build an actively separating, isolating, water-resistant and invisible protective film
- The natural functions of the skin are not affected
- Very good protective efficacy against hydro- and lipophile substances, aggressive chemicals, acids and adhesive powders
- Highly separating efficacy with allergenic substances like powders, dusts or latex
- Does not grease or stick; is quickly absorbed

**Expert opinions:**
Prof. Dr. Harald Voss, TH Aachen, 1991

**Composition:**
Aqua, stearic acid, cetearyl alcohol, triethanolamine, dimethicone, aluminium/magnesium-hydroxide-stearate, isopropylmyristate, cocamidopropyl betaine, propylparaben, methylparaben, ethylparaben, phenoxyethanol, parfum.

**Chemical/Physical data:**
- Consistency: viscous cream
- Colour: white
- Density (20 °C): 0,958 - 0,972 g/cm³
- Ph-value: 7,4 - 8,3

**Application:**
Spread LOTIO C PLUS sparingly on the parts of the skin which are to be protected. You should renew the protective film according to the amount and kind of work and mechanical stress to which the skin is exposed.

**Delivery units:**
75 ml tube
OP-SEPT MEDICAL (ready to use)
Poly-alcoholic hand antiseptic, highly effective and skin friendly

Medical product of the class IIa, CE 0481
Article number 90240 (150ml bottle), 90241 (500ml bottle),
90242 (1-litre bottle), 90243 (5litre canister)

**Type of product:**
Poly alcoholic hand-rub for hygienic and surgical hand disinfection, with excel-

tent skin tolerance due to skin caring and fat restoring additives. Especially for
medical departments and all working areas with an increased risk of infection
and contamination. The skin tolerance is maintained even on long term use.

- spore free filtered
- free from quaternary ammonium compounds

**Certification** by University and Scientific Institutes expert opinions:

Prof. Dr. J. Borneff, Institut Fresenius Traunstein; 1995
Prof. Dr. med. R. Schubert, Frankfurt; 1997, 1998, 2001,
Dr. J. Steinmann, Bremen 2004
(HBV, HIV, Adeno, Rota, HCV, Vaccinia)

Prof. Dr. med. H. G. Sonntag, Heidelberg
M. tuberculosis - 1985

SGS Germany GmbH, Hamburg (MRSA) 1998
Hygiene Nord GmbH, Greifswald 2004

Prof. Werner, Bischofsfen, Austria 2004

Dr. Merk & Kollegen, Ochsenhausen
BVDV 2006

- Op Sept has got the DGHM/VAH-certificate (issued 11.03.2005)

- Op Sept has been proven effective as surgical hand disinfectant according to the
norm prEN 12791, including the 1,5 minutes short time efficacy (3ml) and the 3 hours remanent efficacy (3 ml, 3 min contact) (Prof. Werner, 2004; Hygiene Nord GmbH 2004)

- Op Sept has been proven effective as hygienic hand disinfectant according to the
norm EN 1500 (Prof. Werner, 2004; Hygiene Nord GmbH 2004)

- RKI certificate (Robert Koch Institute) to be issned 12/2005

**Usage and dosage:**
Hygienic disinfection of the hands:
rub into the hands 3 ml OP Sept until drying out; work-in time 30 seconds.

Surgical disinfection of the hands:
rub into the hands and forearms 5 ml Op Sept until drying out (3 minutes); re-

peat procedure.

**Storage conditions:** do not allow temperatures below 0 °C or above 30 °C;
do the product not expose to direct sunlight; keep the store dry
Zertifikat / Certificate

über die Konformität der Wirksamkeitsprüfungen für OP-Sept

OP-Sept

mit den Anforderungskatalogen der Deutschen Gesellschaft für Hygiene und Mikrobiologie (DGHM)

DGHM und VAH bestätigen die Akzeptanz von ärztlich herausgegebenen DGHM-Zertifikaten.

ANTRAGSTELLER / APPLICANT: Laboratorium Dr. Dants
Hoogheweg 35
47904 Kampen

WIRKSTOFFE nach Art und Menge bezogen auf 100 ml bzw. 1 L
Composition and quantity of active substances per 100 ml

70,0% 2-Propylol
0,1% 1,3-Butandiol

Hiermit wird bestätigt, dass das o.g. Produkt für die aerobe bakterielle Desinfektion in dem aufgeführten Anwendungsbereich in den angegebenen Konzentrationen Zeit-Reaktionen als wirksam eingestuft sind.
This is to confirm that the above product was found to be effective for aerobic bacterial disinfection in the application domains listed in the concentrations as specified below.

<table>
<thead>
<tr>
<th>Händedesinfektion / Hand disinfection</th>
<th>Hygienisch / Hygienic</th>
<th>Chirurgisch / Surgical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einwirkungsdauer / Exposure time</td>
<td>Einwirkungsdauer / Exposure time</td>
<td></td>
</tr>
<tr>
<td>min</td>
<td>min</td>
<td></td>
</tr>
<tr>
<td>1/2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

*Die Hände während der gesamten Applikationszeit durch das konzentrierte Präparat feucht halten. / Keep hands well moisturized with the concentrated product during the entire application time.

Das Zertifikat verliert 3 Jahre nach Ausstellung seine Gültigkeit. / The certificate ceases to be valid 3 years after issue.

Bonn, den 11.03.2005

Place/Date

Der Vorsitzende der Desinfektionsmittel-Kommission im VAH / Disinfectant Commission VAH

signature
OP-DERM MEDICAL (ready to use)
Poly-alcoholic skin antiseptic

Medical product of the class IIa, CE 0481
Article number 90250 (200ml bottle), 90251 (1 litre bottle), 90252 (5 litre canister)

**Type of product:**
Poly alcoholic skin antiseptic with excellent skin tolerance for wards, medical practices, **pre- and postoperative use** (also before incisions, punctures, injections). Available in **coloured and colourless** version. The product is in its composition of active substances and effectiveness identical with our hand disinfectant Op Sept.

**Expert opinions/certification according to DGHM:**
- Prof. Dr. Werner, Bischofhofen 2004
- Prof. Dr. Werner, Schwerin 1995
- Prof. Dr. Schubert, Frankfurt 1995
- Prof. Dr. Kramer 1994
- Dr. Merk & Kollegen, Ochsenhausen Vaccinia 2006

This product is in accordance with the quality assurance system DIN EN ISO 9002 and the medical product law DIN EN 46002 (CE) and is **DGHM listed.**

- Op Derm has been proven effective as surgical skin disinfectant according to the **norm prEN 12791**, including the 1,5 minutes short time efficacy (3ml) and the 3 hours remanent efficacy (3 ml 3 min contact) (Prof. Werner, 2004; Hygiene Nord GmbH 2004)

- Op Derm has been proven effective as hygienic skin disinfectant according to the **norm EN 1500** (Prof. Werner, 2004; Hygiene Nord GmbH 2004)

**Area of application:**
Skin disinfection before operations, incisions, punctures and injections.

**Dosage and kind of application:**
Spray the undiluted solution onto the skin which is to be disinfected and rub it in. Let the solution work.

**Skin disinfection:**
Skin with poor sebaceous glands: keep wet 15 sec. before injection and punctures; before punctures of joints, body hollows, hollow organs and before operative interventions keep wet at least 60 sec.
Skin rich of sebaceous glands: before punctures and operations keep wet at least 10 min.

**Contra indications:**
Not suitable for the disinfection of mucous membrane. Do not use it in immediate proximity to the eyes. - Side effects: until now not known.

**Storage conditions:** do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry
Zertifikat / Certificate

Über die Konformität der Wirksamkeitsprüfungen für OP-Derm

ANTRAGSTELLE / APPLICANT: Laboratorium Dr. Deppe
Hooglweg 35
47506 Kamen

WIRKSTOFFE nach Art und Menge bezogen auf 100 ml bzw. 100 g:
Composition and quantity of active substances per 100 ml or 100 g:

70,0% 2-Propanol
0,1% 1,3-Butandiol

Hiermit wird bestätigt, dass das o.g. Produkt für die prophylaktische Desinfektion in dem aufgeführten Anwendungsbereich in folgenden Konzentrations-Zeit-Relationen als wirksam eingestuft wird:
This is to confirm that the above product was found to be effective for prophylactic disinfection in the application domains listed at the concentration/exposure time ratio specified below:

<table>
<thead>
<tr>
<th>Händedesinfektion / Hand disinfection</th>
<th>Hygienisch / Hygienic</th>
<th>Chirurgisch / Surgical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Einwirkungszeit / Exposure time</td>
<td>1/2 min</td>
<td>1 min</td>
</tr>
<tr>
<td>konz.</td>
<td>konz.</td>
<td>konz.</td>
</tr>
<tr>
<td>Einwirkungszeit / Exposure time</td>
<td>3 min</td>
<td>5 min</td>
</tr>
</tbody>
</table>

Das Zertifikat verliert 3 Jahre nach Ausstellung seine Gültigkeit / The certificate expires to be valid 3 years after issue

Bonn, den 28.01.2005
Place/Date

Der Vorsitzende der / Chairman of the
Desinfektionsmittel-Kommission im VAH / Disinfectant Commission in VAH
LOTIO MED
Medical hand- and body wash lotion

Cosmetic product
Article number 90290 (500ml bottle), 90291 (1 litre bottle), 90292 (5 litre canister)

**Type of product:**
- anti-microbial hand- and body wash without soap and alkaline substances
- for cleaning of hands, skin and body
- to be used for showering, bathing, shampooing
- special surfactants guarantee an excellent skin and mucous membrane-tolerance
- even on long term use ph-neutral
- does not affect the natural skin functions
- for medical staff and patients
- with moisturizer (fat restoring agent)
- also suitable for infant areas

**Active agents:**
Anionic and non-ionogenic surfactants in dermatological favourable combination.

**Storage conditions:** do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry

LOTIO SEPT WIPES
Hygienic wipes

Cosmetic product
Article number 90244 (12 x 150 wipes box), 90245 (20 x 150 wipes refill package)

Hygienic ready-to-use wipes for the hygienic disinfection of the hands in all medical areas. The wipes are completely soaked with the poly-alcoholic disinfecting liquid Op Sept Medical.

The liquid in which the wipes are soaked has the following properties:

**Composition:**
100 ml contain:
2-propanol 70ml;
1,3 Butandiol 0.1 ml + fat-restoring agent

**Attention:**
Alcoholic, inflammable, keep away from children

Op Sept Medical is listed in the DGHM register.
Tested by the quantitative method. Excellent skin tolerance.

**Dosage:**
According to demand.

**Ingredients:**
aqua, sodium laureth sulphate, cocamide DEA, disodium laureth-3, sulfosuccinate, cocomidopropyl betaine, magnesium chloride, acid yellow 23, acid blue 3, benzalkonium-chloride, 2-bromo-2-nitro-popane-1, 3-diol, ethylparaben, perfume.

**Available sizes:**
500ml bottle,
1 litre bottle,
5 litre canister

**Shelf life:**
2 years
LOTIO HD
For the washing decontamination of the hands

Cosmetic product
Article number 90260 (500ml bottle), 90261 (1 litre bottle), 90262 (5 litre canister)

Type of product:
Decontaminating and disinfecting hand wash for areas in which soiling of the hands takes place in addition to microbial contamination; for all areas with increased hygiene requirements, like: clinics, doctors practices, ambulances, nursing homes, laboratory areas, industrial areas, public baths, but especially for kitchen and food processing areas.

LOTIO HD is tested according to the guidelines of the DGHM (German Society of Hygiene and Microbiology) and is published in the according list

Spectrum of effect:
· acts quickly and comprehensive already in 30 seconds
· bactericidal, fungicidal incl. salmonellae, yeasts, virus inactivating incl. HBV/HIV
· good cleansing properties also with proteins and fats
· good skin tolerance
· harmless for food

LOTIO HD complies with the high requirements in the food area and is perfectly suited for caring and nursing areas in hospitals and nursing homes.

Application (hygienic):
Distribute thoroughly during 30 seconds 3 ml of undiluted LOTIO HD; afterwards wash while seething with little water and rinse.

Expert opinions/certification according to DGHM:
Prof. Dr. Werner, Schwerin 1993
Prof. Dr. Schubert, Frankfurt 1992
Salmonellae:
Prof. Dr. Schubert, Frankfurt 1993
EN 1499 (hygienic washing of the hands) / EN 12054:
Prof. Dr. Schubert, Frankfurt 2003
Prof. Dr. Werner, Bischofshofen 2003
Prof. Dr. Kramer, Greifswald 2003
HBV/HIV:
Dr. Steinmann, Bremen 2002

Storage conditions: do not allow temperatures below 0 °C or above 30 °C; do the product not expose to direct sunlight; keep the store dry

Composition:
100 g contain:
55g 2-Propanol
2g Cetrimide

Chemical/Physical data:
Consistency: liquid, slightly viscous
Colour: clear
Density (20 °C): 0.880 - 0.910 g/cm3
Ph-value (18  28°C): 5.0 - 5.5

Available sizes:
500ml bottle,
1 litre bottle,
5 litre canister

Shelf life:
3 years
PRODUCT RANGE

Application Aid

- DOSAGE PUMP for easy dispensing of all concentrates (5- and 10 l canister)
- SPOUT for easy filling from canisters
- OPENER for all canisters
- DISPENSER PUMP for easy dispensing from all 500- and 1000-ml-bottles, suitable for all thick and thin liquids such as hand disinfectants, and cleaning and caring products
- DOSING BOTTLE for easy dosing of ready-to-use liquids
- UNIVERSAL DISPENSER made of metal for installation on walls (for 1000-ml-bottles)
- SPRAYER for 1000-ml-bottles for ready-to-use alcoholic disinfectants

PRODUCT OVERVIEW

(including others not mentioned in this catalogue)

INSTRUMENTS:

Cleansing:
  Manual use:
  - Instru Zym enzymatic (anti-microbial)
  - Eco Zym enzymatic (for spraying on instruments after operation and before cleaning)
  - Instru Sol Forte (mild alkaline)
  - Instru Clean (alkaline, powder)

Mechanical use:
  - Labomat E (enzymatic, endoscopes)
  - Labomat SPM (enzymatic)
  - Labomat MA Liquid (alkaline)
  - Labomat MA Powder (alkaline)
  - Labomat KS (rinsing agent)

Disinfecting:
  Manual use:
  - Instru Plus aldehyde based
  - Instru Plus Forte formaldehyde free
  - Endo Star aldehyde free
  - Instru Extra aldehyde free
  - Instru Star aldehyde and q.a.c. free
  - Instru Star r.f.u. ready-for-use (dental)

Mechanical use:
  - Endomat Plus aldehyde based
  - Instru Suc aldehyde free, dental

Maintenance:
  - Instru Care (oil for metal instruments)

Protection:
  - Instru Gel (anti-friction-gel)

HANDS:

Disinfecting:
  - Op Sept Medical
  - Decontaminating:
    - Lotio Sept Hygienic Wipes

Caring:
  - Lotio Lind (lotion)

SKIN:

Disinfecting:
  - Op Derm Medical
  - Lotio Med

Care:
  - Lotio Protect
  - Lotio C Plus

Cleansing:
  - Lotio Derm (spray)
  - Lotio Soft (wipes)

Protection:
  - Lotio Care (spray)

Cooling:
  - Lotio Aktiv (gel)

Bathing:
  - Lotio Vital
  - Lotio San

Bodymilk:
  - Lotio Skin

OTHERS:

- ultra sound gel
- electro cardiogram gel
- catheter gel

Soon available
peracetic acid (instruments, surfaces, dialysis - renal units)
Countries where original Dr. Deppe - products are currently used:

- Albania
- Austria
- Belgium
- Cyprus
- Cyprus
- Estonia
- Georgia
- Germany
- Greece
- Guatemala
- · Hungary
- · Indonesia
- · Italy
- · Jordan
- · Libya
- · Lithuania
- · Lebanon
- · Malaysia
- · Netherlands
- · Netherlands Antilles
- · Poland
- · Romania
- · Saudi Arabia
- · Singapore
- · Slovenia
- · Spain
- · Syria
- · Turkey
PROF...