Medalkan
HYGIENE & DISINFECTION

# The Next Generation of Medical Disinfectants

## Hospitals and clinics product catalog

2024

MADE IN THE E.U.

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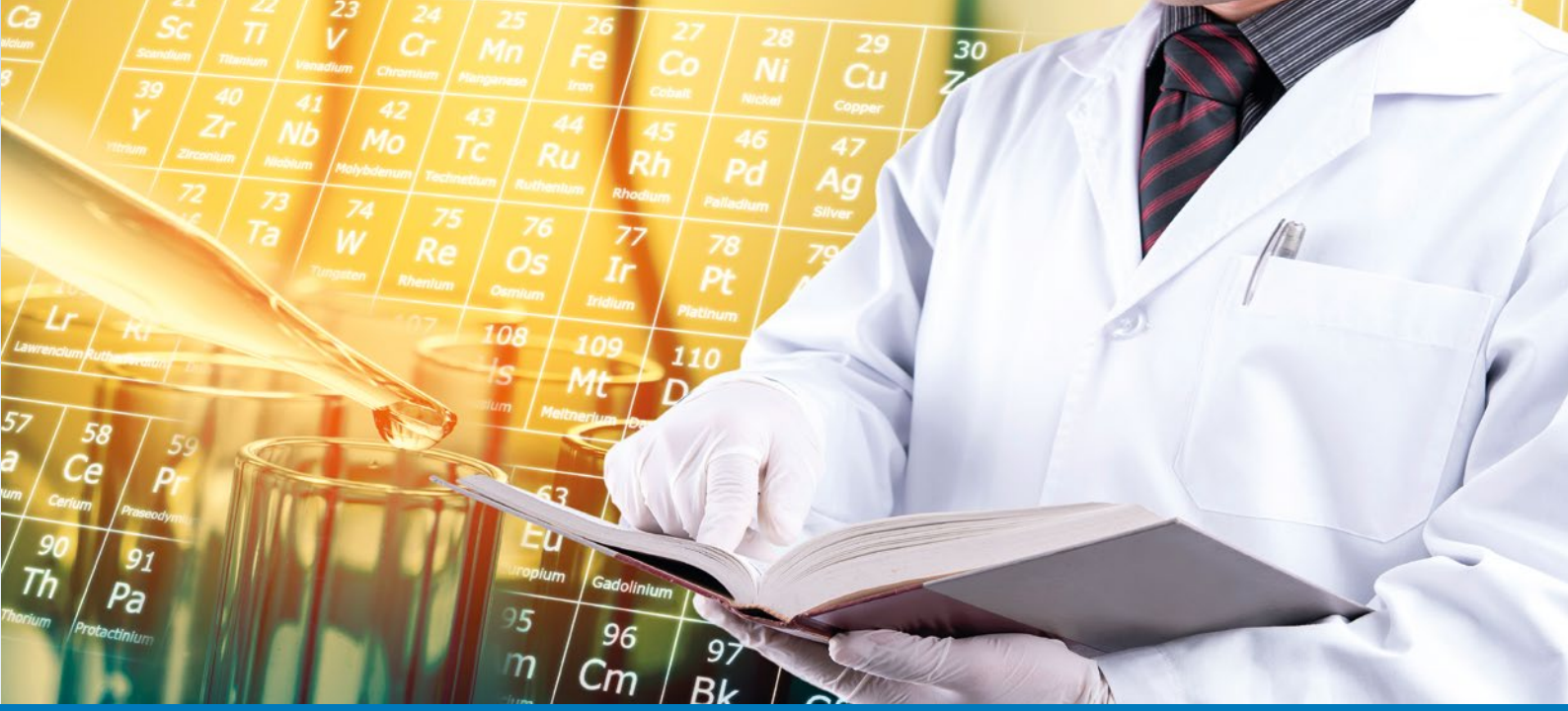
HYGIENE & DISINFECTION

# The Next generation of Medical Disinfectants



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# Our Company

MEDALKAN is a company specialized in the manufacture of hygiene and disinfectant products. Created in 2012, it enjoys a reputation for innovation in the health sector.

MEDALKAN range of products have been designed and developed by a team of Greek and French experts.They are manufactured in Greece using the latest technologies.

Our company enjoys a strategic geographical location on the Mediterranean basin in Athens, Greece. The Port of Piraeus, the main seaport of Athens is one of the largest in Europe.
It is one of the top 10 European container ports and the busiest port platform in the Mediterranean basin.

This gives us quick response to deploy large supplies into Europe and via the Suez canal, Africa, the Middle East and the Far East.

MEDALKAN satisfies the requirements of ISO 9001:2015 and ISO 13485:2016 for the design and manufacture of medical devices.

Our products bear the CE mark in accordance with the 93/42/EEC directive and with the (MDR) 2017/745 regulation for medical devices.

MEDALKAN applies Good Manufacturing Practices (GMP) which guarantees the manufacture and control of products and thus ensure quality.

MEDALKAN offers a complete range of CE marked high-quality cleaning and disinfecting products and meets the most up-to-date requirements for the control of infectious risk.

This includes specialized medical devices for the cleaning and disinfection of surfaces, instruments, endoscopes as well as other specific applications and a hand hygiene product line.

Specifically developed for healthcare professionals, our products are used in hospitals, clinics, dental offices and examination centres. Particular attention was paid to their microbiological properties, efficiency, compatibility with sensitive materials and the environment.

EN ISO 9001 — ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ ΣΤΗΝ ΥΓΕΙΑ Α.Ε.

EN ISO 13485 — ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ ΣΤΗΝ ΥΓΕΙΑ Α.Ε.

ΔΥΒ/1348/2004 — ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ ΣΤΗΝ ΥΓΕΙΑ Α.Ε.

CE 0653

# The European standards for medical devices

| ACTIVITY SPECTRUM | STANDARD PHASE & STEP | TEST CONDITIONS | STRAINS | CONTACT TIME | LOG |
|---|---|---|---|---|---|
| BACTERICIDAL* | **EN 13727** Phase 2/ Step 1 | Conditions: clean / dirty | Pseudomonas aeruginosa<br>Staphylococcus aureus<br>Enterococcus hirae | 60 Min. | 5 Log |
| | **EN 14561** Phase 2/ Step 2 (Optional) | Conditions: clean / dirty | Pseudomonas aeruginosa<br>Staphylococcus aureus<br>Enterococcus hirae | 60 Min. | 5 Log |
| FUNGICIDAL | **EN 13624** Phase 2/ Step 1 | Conditions: clean / dirty | Candida albicans (yeasticidal)<br>Aspergillus brasiliensis (fungicidal) | 60 Min. | 4 Log |
| | **EN 14562** Phase 2/ Step 2 (Optional) | Conditions: clean / dirty | Candida albicans (yeasticidal)<br>Aspergillus brasiliensis (fungicidal) | 60 Min. | 4 Log |
| TUBERCULOCIDAL / MYCOBACTERICIDAL | **EN 14348** Phase 2/ Step 1 | Conditions: clean / dirty | Mycobacterium terrae (Tuberculocidal)<br>M. terrae + M. avium (Mycobactericidal) | 60 Min. | 4 Log |
| | **EN 14563** Phase 2/ Step 2 (Optional) | Conditions: clean / dirty | Mycobacterium terrae (Tuberculocidal)<br>M. terrae + M. avium (Mycobactericidal) | 60 Min. | 4 Log |
| VIRUCIDAL ** (AGAINST ENVELOPED VIRUSES) | **DVV (1)/ RKI (2)(2014)** Phase 2/ Step 1 Limited Virucidal | Conditions: clean / dirty | BVDV (Bovine viral Diarrhea virus)<br>Vaccinia virus | 60 Min. | 4 Log |
| VIRUCIDAL** | **EN 14476** Phase 2/ Step 1 | Conditions: clean / dirty | Poliovirus<br>Adenovirus<br>Norovirus | 60 Min. | 4 Log |
| SPORICIDAL | **EN 14347** Phase 1 | Clean conditions | Bacillus subtilis<br>Bacillus cereus (Optional)<br>Clostridium difficile (Optional) | 60 Min. | 4 Log |
| | **EN 17126** Phase 2/ Step 1 | Clean conditions | Bacillus subtilis<br>Bacillus cereus<br>Clostridium difficile (Optional) | 60 Min. | 4 Log |

* Including all the antibiotic resistant strains as MRSA, Klebsiella pneumoniae, Escherichia coli, streptococcus pneumoniae, etc.
** Included viruses: HIV, BVDV, Vaccinia Virus, HBV (Hepatitis B), HCV (Hepatitis C), Influenza H1N1, H5N1, H1N8, Zika virus, Herpes simplex, Ebola, Coronavirus.

(1) DVV: Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten / German Association for the Control of Virus Diseases
(2) RKI: Robert Koch Institute - German Federal Health Authority

# **Mycobacteria -** Situation and spread

## World situation

According to a 2015 World Health Organization (WHO) report, tuberculosis remains one of the top 10 causes of death worldwide.

Despite tremendous efforts by the United Nations to eradicate the disease by 2030, a global epidemic of tuberculosis persists.

Another challenge that we have to face is the effect of globalization, that is, the dramatic increase in the movement of people and individuals that encompasses tourism activities, refugee diasporas and, soon, migrants climatic.

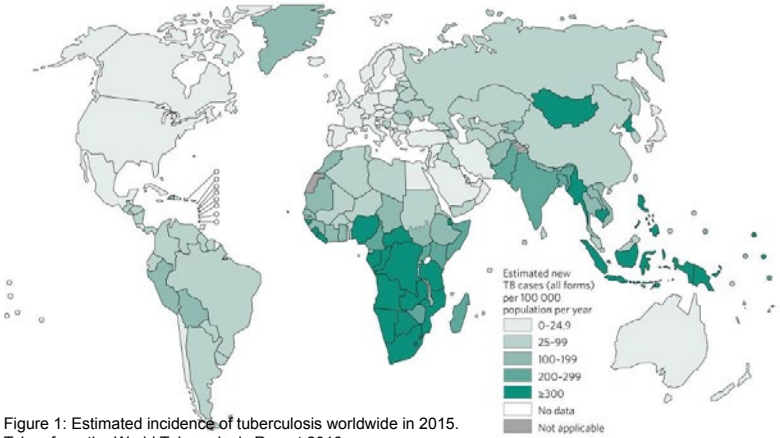


Figure 1: Estimated incidence of tuberculosis worldwide in 2015. Taken from the World Tuberculosis Report 2016.

This ongoing maelstrom has multiple consequences, such as an increasing number of patients infected by nonendemic strains, the spread of multidrug- resistant (MDR) strains from health care-deficient countries, and the frightening specter of the expansion of totally drug-resistant (TDR) strains.

Globally, tuberculosis would affect between 2 and 3 billion people asymptomatically.
Among these, only 5 to 15% will develop the disease during their lifetime, with an increased probability in immunocompromised patients, weakened by age or in a state of malnutrition.

In 2015, according to the World Tuberculosis Report 2016 (WHO), the main figures for the disease are as follows:

- In 2015, tuberculosis remained one of the ten leading causes of death worldwide, ahead of HIV, despite a decline in the number of new cases of 1.5% compared to 2014.
- 10.4 million new cases in 2015 for a total of 6.1 million cases notified and reported to WHO (Figure 1).
- In 2020, a total of 1.5 million people died from TB (214,000 of whom also had HIV infection).lobally, tuberculosis is the 13th leading cause of death and the second due to an infectious disease, behind COVID-19 (and before AIDS).

## Spread of Mycobacteria

Unlike Tuberculosis, which spreads mainly through air and is not known to replicate outside human or animal hosts, atypical mycobacteria are classic opportunistic pathogens with a very wide distribution in biofilms and in natural and engineered environments. They are inherently more resistant to microbicides and many chemotherapeutic agents as well.

Unlike Tuberculosis, mycobacteria may survive on environmental surfaces for days to months. Water and soil are the main reservoirs for environmental mycobacteria, with the nose and mouth as well as damaged soft tissue and skin being major portals of entry.

Environmental mycobacteria in biofilms in rinse water or inside automated endoscope reprocessors themselves can contaminate semicritical medical devices, leading to iatrogenic infections, pseudo-outbreaks or misdiagnoses.

Improperly reprocessed semicritical devices such as gastroscopes and bronchoscopes can be iatrogenic means of spread.

Microbiological testing (EN 13438 tested with Mycobacterium Terrae and Mycobacterium Avium) ensures that **NOSOSEPT 100**, **NOSOFAST TB**, **NOSOFLOOR, NOSOPROTECT, NOSOPROTECT 100** and **NOSOCID PAA** provide the best possible safety against Mycobacterium tuberculosis as well as atypical Mycobacteria.

# Hand Hygiene

Hands are a very important vector of microbial transmission. Hand hygiene can significantly reduce the risk of cross-transmission of infection in healthcare facilities if properly set up.

For this reason, an antisepsis protocol with precise consecutive actions should be scrupulously observed and applied.

Alcohol-based hand sanitizers (with at least 60% alcohol) are largely used in medical areas but are now also recommended for the general public.

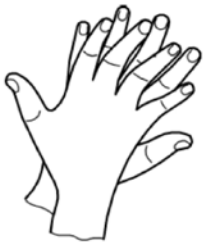
Many situations in a hospital require repeated use of antimicrobial agents (e.g., before invasive procedures, when caring for immuno-compromised patients, critical care areas, intensive care nurseries, etc.). These should be chosen carefully based on their active ingredients and characteristics.

MEDALKAN has developed two alcohol-based antiseptic gels, **NOSODERM GEL 70** and **NOSODERM GEL 80**.
Their compositions have been prepared with a particular attention to combine efficiency and protection of the skin. Considering damaged skin is an open door to microorganisms, an effective antiseptic gel should prevent dryness by optimizing the hydration of the skin.

## Standard hand rubbing procedure

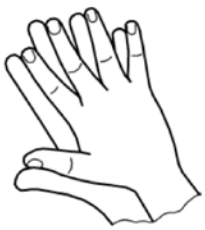
Step 1

Palm to palm



Step 2

Right palm over left dorsum and left palm over right dorsum (five times)

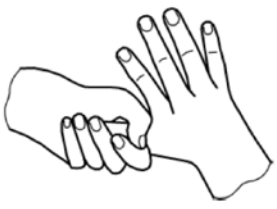


Step 3

Palm to palm with fingers interlaced (five times)

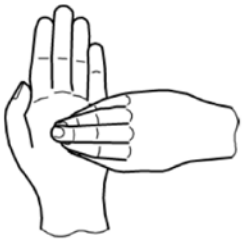
Step 4

Back of fingers to opposing palms with fingers interlocked (five times)



Step 5

Rotational rubbing of right thumb clasped in left palm and vice versa (five times)



Step 6

Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa (five times)

# NOSODERM® GEL

## Hydroalcoholic Hand Cleansing and Antiseptic Gels

**Non sticky and non greasy formulations**

**Leaves the skin clean, fresh and silky**

DERMATOLOGICALLY TESTED

**NOSODERM GEL 70** and **NOSODERM GEL 80** have a neutral pH and have been dermatologically tested on sensitive skin.

## NOSODERM GEL 80
### Antiseptic Hydroalcoholic Hand Gel

NOSODERM GEL 80 is an antiseptic gel with a broad antimicrobial spectrum. It contains 80% ethyl alcohol. Enriched with moisturizing active ingredients, it preserves the skin hydrolipidic film and thus allows repeated use.

It is recommended for antisepsis:

- Pre and post operative
- Before and after direct contact with a patient or his immediate environment
- After contact with blood, body fluids or contaminated surfaces
- Before an aseptic or invasive procedure (samples, injections, venous passages, dressings, etc.)

### Composition

Alcohol denat, Aqua (Water), Propanediol, Glycerin, Acrylates/C10-30 Alkyl acrylate cross polymer, Myristyl alcohol, Panthenol.

**NOSODERM GEL 80 is a biocide.**
Use biocidal products with caution.
Before use, read the label and the product information.

### Disinfecting properties

| ACTIVITY SPECTRUM | STANDARD | STRAINS | CONTACT TIME |
|---|---|---|---|
| BACTERICIDAL* | EN 13727 | Pseudomonas aeruginosa<br>Staphylococcus aureus<br>Escherichia coli<br>Enterococcus hirae | 15 sec. |
| FONGICIDAL | EN 13624 | Candida Albicans | 15 sec. |
| VIRUCIDAL** | EN 14476 | Adenovirus, Norovirus<br>Polyovirus | 30 sec.<br>60 sec. |
| TUBERCULOCIDAL | EN 14348 | Mycobacterium Terrae<br>(Surrogate. M. tuberculosis) | 30 sec. |
| MYCOBACTERICIDAL | EN 14348 | Mycobacterium Terrae<br>Mycobacterium Avium | 30 sec. |
| HYGIENIC HANDRUB - Efficacy test carried out under real conditions | EN 1500<br>(Phase 2 / Step 2) | Escherichia coli | 30 sec. |
| SURGICAL HAND DISINFECTION - Efficacy test carried out under real conditions | EN 12791<br>(Phase 2 / Step 2) | Resident microbial flora | 2 x 60 sec. |

* Including all antibiotic resistant bacteria such as MRSA, Escherichia coli, Klebsiella pneumoniae, Streptococcus pneumoniae, etc.)
** Including enveloped viruses such as BVDV, Vaccinia, HBV, HIV, HCV, Ebola, Herpes, Influenza H1N1, H5N1, Coronavirus

### NOSODERM GEL 80 - Packaging

- 500 ml. bottle with pump (Ref. 20053)
- 1 litre bottle with flip top cap (Ref. 20055)
- 5 litre canister (Ref. 20054)

## NOSODERM GEL 70
### Hydroalcoholic Hand Cleansing Gel

NOSODERM GEL 70 is a hand cleansing gel with a mild antiseptic action. It contains 70% ethyl alcohol.
Its moisturizing composition prevents skin dryness and provides a pleasant feeling of freshness and cleanliness.

### Properties

- Contains 70% (v/v) of Ethanol
- Dermatogically tested on sensitive skins
- Neutral pH
- Protects the integrity of the hydrolipidic film and limits moisture loss
- Leaves the skin clean, fresh and silky

### NOSODERM GEL 70 - Packaging

- 80 ml. bottle with flip top cap (Ref. 20044)
- 500 ml. bottle with pump (Ref. 20040)
- 1 litre bottle with flip top cap (Ref. 20041)
- 5 litre canister (Ref. 20045)

### Optional dispensers (available for both gels)

- Dosing pump for 1 litre bottle (Ref. 20046)
- 500 ml. touchless dispenser for desk or wall (Ref. 20047)
- Elbow dispenser with lock and wall mount (Ref. 20048)

### Composition

Alcohol denat, Aqua (Water), Propanediol, Glycerin, Acrylates/C10-30 Alkyl acrylate cross polymer, Myristyl alcohol, Dicaprylyl carbonate, Tetrahydroxypropyl ethylenediamine, Bisabolol, Panthenol, Dimethicone.

**NOSODERM GEL 70 is registered as a cosmetic product.**
C.P.N.P Registration number: 3642922.

# NOSOSEPT® 100

## Fast acting broad spectrum surface disinfectant

Active in 30”

NOSOSEPT 100 is a broad spectrum antimicrobial disinfectant spray specially formulated for the rapid cleaning and disinfection of surfaces of medical devices. Active in 30 seconds, its use after each session prevents cross-contamination between patients.

It is recommended for surfaces of medical devices in direct contact with patients and medical personnel such as trolleys, benches, examination tables, operating room furniture, etc.

NOSOSEPT 100 has excellent disinfectant properties, a mild odor and leaves no residues after drying.


## Properties

- Active in 30 seconds
- Leaves no residue after drying
- Does not affect the medical equipment
- Bactericidal, fungicidal, tuberculocidal, mycobactericidal
- Virucidal (HBV, HIV, HCV,Herpes, Vaccinia, BVDV, Influenza, Ebola, Coronavirus, Rotavirus,...)
- Does not contain phenols, aldehydes, chlorine or EDTA

## Disinfecting properties

| ACTIVITY SPECTRUM | STANDARD | STRAINS | CONTACT TIME |
|---|---|---|---|
| **BACTERICIDAL*** (Dirty conditions) | EN 13727 | Pseudomonas aeruginosa<br>Staphylococcus aureus<br>Enterococcus hirae | 30 sec. |
| **FUNGICIDAL** (Dirty conditions) | EN 13624 | Candida Albicans<br>Aspergilus Brasiliensis (Fungicidal) | 30 sec.<br>5 min. |
| **VIRUCIDAL** (Dirty conditions) | DVV[1]/RKI[2] 2014 | BVDV, Vaccinia, HBV, HIV, HCV, Ebola, Herpes, Influenza H1N1, H5N1, Coronavirus | 30 sec. |
| | EN 14476 | Rotavirus | |
| **TUBERCULOCIDAL** (Dirty conditions) | EN 14348 | Mycobacterium Terrae (Surrogate M. tuberculosis) | 3 min. |
| **MYCOBACTERICIDAL** (Dirty conditions) | EN 14348 | Mycobacterium Terrae<br>Mycobacterium Avium | 3 min. |

* Including all antibiotic resistant bacteria such as MRSA, Escherichia coli, Klebsiella pneumoniae, Streptococcus pneumoniae, etc.)
(1) DVV: Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten (German Association for the Control of Virus Diseases)
(2) RKI: Robert Koch Institute - German Federal Health Authority

## Certifications

- CE mark according to the medical devices Directive (Directive 93/42/EEC)
- Medical device class IIa

## Packaging

- One litre bottle with spray (Ref. 20003)
- 5 litre refill canister (Ref. 20004)

## Physical properties

| | |
|---|---|
| Appearance: | Transparent solution |
| Density: | 0.97 g/cm$^3$ at 20˚C |
| pH: | 9.0-9.6 at 20˚C |
| Odour: | Mild (alcohol) |
| Storage: | 5˚C - 35˚C |
| Stability: | 3 Years |
| Biodegradability: | According to OCDE 301D |

## Composition

Isopropyl alcohol, didecyl-dimethyl ammonium chloride, N-(3-aminopropyl)-N dodecylpropano-1,3-diamine, excipients.

## Compatibility

Due to its low alcohol content, NOSOSEPT 100 is friendly to sensitive surfaces while simultaneously providing extremely rapid disinfection times.





**NOSOSEPT 100** is manufactured in the EU. **MEDALKAN** satisfies the requirements of **ISO 9001:2015** for quality management system and the requirements of **ISO 13485:2016** for the design and manufacture of medical devices.

# NOSOFAST TB®

## Foaming disinfectant spray for medical equipment surfaces

Alcohol free

NOSOFAST TB is a foaming disinfectant spray with a broad antimicrobial spectrum of activity. It combines excellent cleaning and disinfecting properties and ensures the protection of patients and staff.

Its alcohol-free formulation is ideal for the rapid disinfection of sensitive medical equipment surfaces, such as incubators, monitors, plexiglass, etc.
It is also suitable for all surfaces of medical equipment such as beds, stretchers, work benches and all other medical devices.

NOSOFAST TB does not leave any residue after drying, is odorless and does not affect the medical equipment.


## Properties

- Leaves no residue after drying
- Does not affect the medical equipment
- Virucidal (HBV, HIV, HCV,Herpes, Vaccinia, BVDV, Influenza H1N1, H5N1, Ebola, Coronavirus...)
- Bactericidal, fungicidal, tuberculocidal, mycobactericidal
- Does not contain phenols, aldehydes, chlorine or EDTA

## Disinfecting properties

| ACTIVITY SPECTRUM | STANDARD | STRAINS | CONTACT TIME |
|---|---|---|---|
| **BACTERICIDAL*** (Dirty conditions) | EN 13727 | Pseudomonas aeruginosa Staphylococcus aureus Enterococcus hirae | 30 sec. |
| **FUNGICIDAL** (Dirty conditions) | EN 13624 | Candida Albicans | 30 sec. |
| **VIRUCIDAL** (Dirty conditions) | DVV(1)/RKI(2) 2014 | BVDV, Vaccinia, HBV, HIV, HCV, Ebola, Herpes, Influenza H1N1, H5N1, Coronavirus | 2 min. |
| **TUBERCULOCIDAL** (Dirty conditions) | EN 14348 | Mycobacterium Terrae (Surrogate M. tuberculosis) | 15 min. |
| **MYCOBACTERICIDAL** (Dirty conditions) | EN 14348 | Mycobacterium Terrae Mycobacterium Avium | 15 min. |

* Including all resistant bacteria such as MRSA, Escherichia coli, Klebsiella pneumoniae, Streptococcus pneumoniae, etc.)

(1) DVV: Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten (German Association for the Control of Virus Diseases)

(2) RKI: Robert Koch Institute - German Federal Health Authority

## Certifications

- CE mark according to the medical devices Directive (Directive 93/42/EEC)
- Medical device class IIa

## Packaging

- One litre bottle with spray (Ref. 20042)
- 5 litre refill canister (Ref. 20043)

## Physical properties

| | |
|---|---|
| Appearance: | Transparent solution |
| Density: | 0.99 g/cm$^3$ at 20˚C |
| pH: | 9.5-10.5 at 20˚C |
| Odour: | Neutral |
| Storage: | 5˚C - 35˚C |
| Stability: | 3 years |
| Biodegradability: | According to OCDE 301D |

## Composition

N-(3-aminopropyl)-N-dodecylpropano-1,3-diamine, non ionic surfactants <5%, corrosion inhibitor, pH regulator, excipients

## Compatibility

NOSOFAST TB is compatible with most materials such as stainless steel, aluminum, glass, ceramics, hard plastics, ebonite, plexiglass, etc.

# NOSOFLOOR®

## Highly concentrated disinfectant for medical equipment surfaces

NOSOFLOOR is a high efficacy concentrated solution for the daily cleaning and disinfection of medical device' surfaces in hospitals, clinics and other health institutions. It is used for the routine disinfection in operating rooms, intensive care units, patient-near areas, etc.

NOSOFLOOR combines a broad spectrum of antimicrobial activity and a very good cleaning power.

Its tuberculocidal and mycobactericidal properties are particularly indicated for use in operationg rooms where projections on surfaces are numerous and represent a high risk of contamination.

NOSOFLOOR has an excellent compatibility with most materials.


## Properties

- Excellent cleaning properties
- Very econimical: from 0,25% to 1% dilution
- Does not affect the medical equipment
- Leaves no residue after drying
- Bactericidal, fungicidal, tuberculocidal, mycobactericidal
- Virucidal (HBV, HIV, HCV,Herpes, Vaccinia, BVDV, Influenza, Ebola, Coronavirus...)
- Does not contain phenols, aldehydes, chlorine or EDTA

## Disinfecting properties

| ACTIVITY SPECTRUM | STANDARD | STRAINS | DOSAGE ml/l - (%) | CONTACT TIME |
|---|---|---|---|---|
| **BACTERICIDAL*** (Dirty conditions) | EN 13727 | Pseudomonas aeruginosa Staphylococcus aureus Enterococcus hirae | 2,5 ml/l - 0.25% | 5 Min. |
| **FUNGICIDAL** (Dirty conditions) | EN 13624 | Candida Albicans | 2,5 ml/l - 0.25% | 5 Min. |
| **VIRUCIDAL** (Dirty conditions) | DVV(1)/RKI(2) 2014 | BVDV, Vaccinia, HBV, HIV, HCV, Ebola, Herpes, Influenza H1N1, H5N1, Coronavirus | 10 ml/l - 1% | 15 Min. |
| | | | 7,5 ml/l - 0.75% | 30 Min |
| **TUBERCULOCIDAL** (Dirty conditions) | EN 14348 | Mycobacterium Terrae (Surrogate M. tuberculosis) | 20 ml/l - 2% | 15 Min. |
| | | | 10 ml/l - 1% | 60 Min. |
| **MYCOBACTERICIDAL** (Dirty conditions) | EN 14348 | Mycobacterium Terrae Mycobacterium Avium | 10 ml/l - 1% | 60 Min. |

* Including all antibiotic resistant bacteria such as MRSA, Escherichia coli, Klebsiella pneumoniae, Streptococcus pneumoniae, etc.)
(1) DVV: Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten (German Association for the Control of Virus Diseases)
(2) RKI: Robert Koch Institute - German Federal Health Authority

## Certifications

- CE mark according to the medical devices Directive (Directive 93/42/EEC)
- Medical device class IIa

## Packaging

- 5 litre canister (Ref. 20025)
- Dosing pump for 5 litre canister (Ref. 20023)

## Physical properties

| | |
|---|---|
| Appearance: | Transparent light pink solution |
| Density: | 0.99 g/cm$^3$ at 20˚C |
| pH: | 12.0-12.8 at 20˚C |
| pH (1%): | 9.5-10.5 at 20˚C |
| Odour: | Natural eucalyptus essence |
| Storage: | 5˚C - 35˚C |
| Stability: | 3 Years |
| Biodegradability: | According to OCDE 301D |

## Composition

N-(3-aminopropyl)-N-dodecylpropano-1,3-diamine, didecyl-dimethyl ammonium chloride, <5% non-ionic surfactants, isopropyl alcohol, corrosion inhibitor, excipients.

## Compatibility

NOSOFLOOR is compatible with most materials such as stainless steel, aluminum, glass, ceramics, hard plastics, linoleum, ebonite, etc.





**NOSOFLOOR** is manufactured in the EU. **MEDALKAN** satisfies the requirements of **ISO 9001:2015** for quality management system and the requirements of **ISO 13485:2016** for the design and manufacture of medical devices.

# Endoscope reprocessing
## The cleaning process

Endoscopes are widely used as a valuable diagnostic and therapeutic tool; however, it has been reported that health care-associated outbreaks of infections can be more frequently linked to contaminated endoscopes than to any other medical device.

Endoscopes are in contact with different body fluids, and the channels provide an ideal surface for bacterial adhesion. Viable bacterial cells can be detected on many endoscopes even after cleaning and disinfection processes.

The main reason for this is that under natural conditions, most bacteria occur in the form of biofilms.

They adhere to surfaces and are embedded in a self-produced layer of extracellular polymeric substances (EPS). EPS provide structural integrity to biofilms and protect the bacteria against environmental influences such as UV irradiation, antibiotics, and disinfection and make them much more tolerant to these stresses, It is a huge challenge to avoid and remove biofilms, especially in moist environments such as used endoscope channels.

**Cleaning is the critical step in endoscopes reprocessing**

It consists of the mechanical cleaning of internal an external surfaces of the endoscope. This includes brushing them carefully with a dertergent solution, and then flushing thoroughly with soft water. The purpose of cleaning is to remove all organic and inorganic materials from the internal and external surfaces of flexible endoscopes.

If the manual cleaning, brushing and rinsing steps are not properly carried out, protein debris can harden and lead to formation of biofilm on the biopsy channel of the endoscope. Inadequate cleaning can thus result in material remaining on the endoscope surfaces which prevents disinfectant reaching all parts of potentially contaminated surfaces.

For this reason, the endoscope should be cleaned with an enzymatic detergent immediately after use and prior to the disinfection step.

**NOSOZYM** and **NOSOZYM 6 PLUS** contain a combination of specific and highly stabilized enzymes. The enzymes break down the soil into tiny fragments, making it water soluble and thus easier to remove by rinsing.

Use **NOSOZYM** or **NOSOZYM 6 PLUS** for endoscope cleaning:

- by manual cleaning
- in automated reprocessor (Please follow the manufacturer's instructions)

NOSOZYM and NOSOZYM 6 PLUS are compatible with all major brands of endoscopes.
They have been tested and approved by PENTAX MEDICAL®.

# NOSOZYM®

## Enzymatic detergent for surgical instruments and endoscopes

NOSOZYM is a very efficient concentrated tri-enzymatic cleaner for surgical instruments and endoscopes.

NOSOZYM contains a combination of enzymes (protease, lipase, amylase) that degrade proteins, fats, and blood residues. Its non-foaming and neutral pH formulation is totally adapted to the cleaning of flexible endoscopes.

This synergy of enzymes removes biofilm from the internal and external surfaces of the biopsy chains of endoscopes.

NOSOZYM can be used in ultrasonic bath, in automated endoscope washer, in instrument washers or in immersion bath.

NOSOZYM is approved by PENTAX MEDICAL® and compatible with all major brands of endoscopes.


### Properties

- A new generation of enzymes for an enhanced cleaning action
- Effectively removes organic residues
- Dissolves the biofilm
- Very economical (0.15% to 0.5% dilution)
- Does not foam
- Prevents corrosion and instrument discoloration
- Compatible with heat-sensitive instruments
- Does not contain aldehydes, phenols, chlorine or EDTA

### Composition

Protease, lipase, amylase, non ionic surfactants <5%, corrosion inhibitor, pH regulator, excipients.

### Compatibility

NOSOZYM is compatible with most materials such as stainless steel, aluminum, glass, ceramics, hard plastics, ebonite, etc.

### Ultrasonic bath

NOSOZYM can be used in all common types of ultrasonic baths.

### Certifications

- CE mark according to the medical device Regulation (MDR) (Regulation 2017/745)
- Medical device class I

### Packaging

- 5 litre canister (Ref. 20022)
- Dosing pump for 5 litre canister (Ref. 20023)

### Physical properties

| | |
|---|---|
| Appearance: | Transparent orange solution |
| Density: | 1.02 g/cm$^3$ at 20˚C |
| pH: | 7.0-8.0 (neutral) at 20˚C |
| pH (0,5%): | 7.0-8.0 (neutral) at 20˚C |
| Odour: | Neutral |
| Storage: | 5˚C - 35˚C |
| Stability: | 3 Years |
| Biodegradability: | According to OCDE 301D |

### Recommended dosage table

| CLEANING METHOD | RECOMMENDED DOSAGE (%) * | RECOMMENDED DOSAGE (ml/l) | WATER TEMP. (°C) | CONTACT TIME |
|---|---|---|---|---|
| IN IMMERSION BATH | 0,5% - 1% | 5 ml/l -10 ml/l | 20 - 60 °C | 1 - 10 min |
| IN ULTRASONIC BATH | 0,2% - 0,5% | 2 ml/l - 5 ml/l | 45 - 60 °C | 1 - 5 min |
| IN AUTOMATED REPROCESSOR | 0,15% - 0,5% | 1,5 ml/l - 5 ml/l | 45 - 60 °C | 1 - 5 min ** |

* Always adjust the dosage and contact time depending on the degree of contamination and cleaning method you follow. Recommended dosages can be adjusted or exceeded according to the quality and temperature of the water and the type of washer used.
** According to the recommendations of the washer's manufacturer.





**NOSOZYM** is manufactured in the EU. **MEDALKAN** satisfies the requirements of **ISO 9001:2015** for quality management system and the requirements of **ISO 13485:2016** for the design and manufacture of medical devices.

# NOSOZYM 6 PLUS®

## Multi-enzymatic cleaner for surgical instruments and endoscopes

NOSOZYM 6 PLUS is an very concentrated multienzymatic detergent specially formulated for cleaning endoscopes and surgical instruments.

Thanks to the synergy of 7 enzymes (protease, lipase, amylase, pectinase, mannanase and two cellulases), it dissolves rapidly all types of organic residues such as proteins, lipids, starch, cellulose, polysaccharides and blood deposits. It effectively removes biofilm while preserving endoscope materials.

The enhanced formulation of NOSOZYM 6 PLUS will prevent instrument corrosion and discoloration while keeping the instrument's initial brilliance.

NOSOZYM is approved by PENTAX MEDICAL® and compatible with all major brands of endoscopes.

NOSOZYM 6 PLUS can be used in ultrasonic baths, immersion baths or in automatic washers.


### Properties

- A synergy of 7 highly stabilized enzymes for a powerful cleaning action
- Effectively removes organic residues
- Dissolves the biofilm
- Very economical (0.1% to 0.5% dilution)
- Does not foam
- Prevents corrosion and instrument discoloration
- Compatible with heat-sensitive instruments
- Does not contain aldehydes, phenols, chlorine or EDTA

### Composition

Protease, lipase, amylase, pectinase, mannanase, cellulases, non ionic surfactants <5%, corrosion inhibitor, pH regulator, excipients.

### Compatibility

NOSOZYM 6 PLUS is compatible with most materials such as stainless steel, aluminum, glass, ceramics, hard plastics, ebonite, etc.

### Ultrasonic bath

NOSOZYM 6 PLUS can be used in all common types of ultrasonic baths.

### Certifications

- CE mark according to the medical device Regulation (MDR) (Regulation 2017/745)
- Medical device class I

### Packaging

- 5 litre canister (Ref. 20033)
- Dosing pump for 5 litre canister (Ref. 20023)

### Physical properties

| | |
|---|---|
| Appearance: | Transparent orange solution |
| Density: | 1.02 g/cm$^3$ at 20˚C |
| pH: | 7.0-8.0 (neutral) at 20˚C |
| pH (0,5%): | 7.0-8.0 (neutral) at 20˚C |
| Odour: | Neutral |
| Storage: | 5˚C - 35˚C |
| Stability: | 3 Years |
| Biodegradability: | According to OCDE 301D |

### Recommended dosage table

| CLEANING METHOD | RECOMMENDED DOSAGE (%) * | RECOMMENDED DOSAGE (ml/l) | WATER TEMP. (°C) | CONTACT TIME |
|---|---|---|---|---|
| IN IMMERSION BATH | 0,2% - 0,5% | 2 ml/l - 5 ml/l | 20 - 60 °C | 1 - 5 min |
| IN ULTRASONIC BATH | 0,2% - 0,5% | 2 ml/l - 5 ml/l | 45 - 60 °C | 1 - 5 min |
| IN AUTOMATED REPROCESSOR | 0,1% - 0,5% | 1 ml/l - 5 ml/l | 45 - 60 °C | 1 - 5 min ** |

* Always adjust the dosage and contact time depending on the degree of contamination and cleaning method you follow. Recommended dosages can be adjusted or exceeded according to the quality and temperature of the water and the type of washer used.
** According to the recommendations of the washer's manufacturer.

# Endoscope reprocessing

## Endoscope high level disinfection

There are seven steps involved in the reprocessing of endoscopes: precleaning, cleaning, rinsing, disinfection, rinsing, drying, and finally storage.

High-level disinfection is recommended after the cleaning and rinsing processes. The endoscope and its components should be completely immersed in a high-level disinfectant solution, ensuring that all channels are well perfused.

Selection of high-level disinfectants should be based on Conformité Européene (CE), US Food and Drug Administration (FDA) or Korean Food and Drug Administration approval.
The appropriate exposure time and temperature for high-level disinfection are specific to each disinfectant and its use concentration.

Chemicals commonly used for the high-level disinfection of endoscopes and other semi-critical medical devices include aldehydes (i.e., glutaraldehyde and ortho-phthalaldehyde) and peracetic acid.

### HIGH LEVEL DISINFECTION CHEMISTRY COMPARATIVE CHART

| | GLUTARALDEHYDE (GA) | ORTHO-PHTHALALADEHYDE (OPA) | NOSOCID PAA (PAA) |
|---|---|---|---|
| PERFORMANCE | • Coagulates blood and fixes tissue to surfaces favouring the formation of Biofilm<br>• Periodic evaluation of the lung function of the professionals who handle the solution is required<br>• No activation required<br>• Volatile<br>• Good stability (14 to 28 days) | • Volatile, but much less than glutaraldehyde<br>• Neutralization of the product is recommended prior to disposal<br>• More expensive than glutaraldehyde<br>• No activation required<br>• No irritating odor<br>• Good stability (7 to 14 days) | • Does not coagulate blood or fix tissues to surfaces<br>• Full disinfection spectrum in 5 minutes<br>• Eliminates biofilm<br>• No adverse health effects to operators under normal operating conditions<br>• Odor or irritation not significant<br>• Low temperature liquid immersion sterilization<br>• Environmentally friendly.<br>• Decomposes in oxygen and water<br>• Good stability (15 days) |
| EFFICIENCY | • Low and slow sporicidal and mycobactericidal activity at room temperature | • Low and slow activity on bacterial spores at room temperature | • Rapid sterilization<br>• Rapid sporicidal activity<br>• Full disinfection spectrum in 5 minutes at room temperature<br>• Sporicidal on Bacillus cereus and on all bacterial spores (tested according to the last standard EN 17126:2019 )* |
| SAFETY | • Sensitizing, irritant to skin, eyes and respiratory tract from glutaraldehyde vapors<br>• Ventilation is highly recommended<br>• Allergic contact dermatitis<br>• Adverse effects for patients after insufficient rinsing of devices<br>• Can cause colitis in patients<br>• The negative impact of aldehydes on human health has been well-documented.<br>• Environmental health and safety measures are expensive | • Irritant for eyes and respiratory tract<br>• Stains skin<br>• Little data on hazards of long−term exposure and on safe exposure levels<br>• Anaphylaxis reactions with repeated cystoscopy in cancer patients | • Irritant if in contact with eyes<br>• No other adverse effect |
| MATERIAL COMPATIBILITY | • Excellent materials compatibility | • Excellent materials compatibility | • Excellent materials compatibility |

MEDALKAN has formulated **NOSOCID PAA**, high level disinfectant based on peracetic acid and hydrogen peroxide for the cold sterilization of thermosensitive instruments and endoscopes. Made up of a base solution and an activator, the mixed solution is ready-to-use and lasts 15 days. Peracetic acid concentration is easy to check with **NOSOCID PAA TEST STRIPS** to ensure optimal efficiency.

**NOSOCID PAA** provides a full spectrum of antimicrobial activity (bactericidal, fungicidal, fully virucidal, tuberculocidal, mycobactericidal and sporicidal*) in a contact time of only 5 minutes.

* **NOSOCID PAA** has been tested according to DIN EN 17126:2019 which is the latest standard for the evaluation of sporicidal activity of chemical disinfectants in the medical area.

# NOSOCID PAA®

## High level disinfectant based on peracetic acid

NOSOCID PAA is a high level disinfectant especially formulated for the cold sterilization of thermosensitive instruments and endoscopes. It is based on a synergy of peracetic acid and hydrogen peroxide.

It combines a broad spectrum of antimicrobial activity, rapid contact times and an enhanced material compatibility.

It is recommended for the cold sterilisation of all types of endoscopes (bronchoscopes, gastroscopes, duodenoscopes,naso-laryngo-pharyngoscopes, laparoscopes, etc.), surgical instruments, anesthetic and heat-sensitive medical devices.

NOSOCID PAA does not fix proteins, eliminates biofilm and is effective even in the presence of organic materials.
Formulated with very effective corrosion inhibitors, it is safe for most common endoscope materials.


## Properties

- Ready-to-use solution
- Effective even with the presence of proteins
- Compatible with most common sensible materials
- Compatible with heat-sensitive instruments
- Rapid action: full spectrum in 5 min.
- Stability of the ready-to-use solution: 15 days
- Easy checking of PAA concentration with test strips
- No aldehydes, safe for the user
- Decomposes into water and oxygen

## Disinfecting properties

| ACTIVITY SPECTRUM | STANDARD | STRAINS | CONTACT TIME |
|---|---|---|---|
| **BACTERICIDAL*** (Clean conditions) | EN 13727:2012 + A2:2015 (phase 2 / step 1)<br>EN 14561:2006 (phase 2 / step 2) | Pseudomonas aeruginosa<br>Staphylococcus aureus<br>Enterococcus hirae | 5 Min. |
| **FUNGICIDAL** (Clean conditions) | EN 13624:2013 (phase 2 / step 1)<br>EN 14562:2006 (phase 2 / step 2) | Candida Albicans<br>Aspergillus Brasiliensis | 5 Min. |
| **VIRUCIDAL**** (Clean conditions) | EN 14476:2013 + A2:2019 (phase 2 / step 1) | Adenovirus, Norovirus<br>Polyovirus | 5 Min. |
| **TUBERCULOCIDAL** (Clean conditions) | EN 14348:2005 (phase 2 / step 1)<br>EN 14563:2009 (phase 2 / step 2) | Mycobacterium Terrae<br>(Surrogate M. tuberculosis) | 5 Min. |
| **MYCOBACTERICIDAL** (Clean conditions) | EN 14348:2005 (phase 2 / step 1)<br>EN 14563:2009 (phase 2 / step 2) | Mycobacterium Terrae<br>Mycobacterium Avium | 5 Min. |
| **SPORICIDAL***** (Clean conditions) | EN 17126:2019 (phase 2 / step 1) | Bacillus subtilis<br>Clostridioides difficille<br>Bacillus cereus | 5 Min. |

* Including all antibiotic resistant bacteria such as MRSA, Escherichia coli, Klebsiella pneumoniae, Streptococcus pneumoniae, etc.)
** Including enveloped viruses such as BVDV, Vaccinia, HBV, HIV, HCV, Ebola, Herpes, Influenza H1N1, H5N1, Coronavirus
*** NOSOCID PAA has been tested according to DIN EN 17126:2019 which is the latest standard for the evaluation of sporicidal activity of chemical disinfectants in the medical area

## Packaging

- 5 litre canister (base + activator solution) - Ref. 20050
- NOSOCID PAA test strips (tube of 50 strips) - Ref. 20051

## Physical properties

| | |
|---|---|
| Appearance: | Transparent solution |
| Density: | 1,02 g/cm$^3$ at 20˚C |
| pH: | 4.5-6.0 (neutral) at 20˚C |
| Odour: | Mild (acetic acid) |
| Storage: | 5˚C - 35˚C |
| Stability: | 24 months |
| Biodegradability: | According to OCDE 301D |

## Compatibility

NOSOCID PAA has been tested on most common materials such as stainless steel, polycarbonates, polyurethane, polysulfone, polyethylene, aluminum, glass, silicones, hard plastics and elastomers.

NOSOCID PAA is not compatible with copper, iron and brass. Compatibility with sensitive materials and plated alloys should be tested before use.

*Corrosion tests have been carried out by an independent national laboratory in order to ensure safety and transparency. Test report is available upon request.*

## Composition

Peracetic acid, hydrogen peroxide, acetic acid, corrosion inhibitors, pH regulator, excipients.

## Certifications

- CE mark according to the medical devices Directive (Directive 93/42/EEC)
- Medical device class IIb

**NOSOCID PAA** is manufactured in the EU. **MEDALKAN** satisfies the requirements of **ISO 9001:2015** for quality management system and the requirements of **ISO 13485:2016** for the design and manufacture of medical devices.

# Instrument disinfection
## The importance of pre-disinfection

Disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients.

Cleaning should always precede high-level disinfection and sterilization. Current disinfection and sterilization guidelines should be strictly followed.

A pre-disinfection procedure is highly recommended for reusable and immersible medical devices prior to sterilization. It consists of immersing soiled surgical instruments in a detergent and disinfectant solution like **NOSOPROTECT** before their reprocessing at the Central Sterile Services Department (CSSD).

This soaking procedure should be performed as soon as possible and as close as possible to the operating room.

If the distance between the operating room and the CSSD is reduced, instrument soaking can be done directly in the CSSD. If the distance is too long, soiled instruments should be pre-treated immediately after use and kept moisturized by a disinfecting sprayable solution like **NOSOPROTECT 100** in order to limit the risk of transmission between the operating room and the CSSD.

Therefore, MEDALKAN has formulated:

- **NOSOPROTECT**, highly concentrated mycobactericidal instrument disinfectant.
- **NOSOPROTECT 100**, foaming disinfectant spray for instrument pre-treatment.

They both combine a powerful cleaning action with a broad spectrum of antimicrobial activity (including tuberculosis and mycobacteria).

Since medical and surgical instruments represent a large investment to any healthcare facility, both **NOSOPROTECT** and **NOSOPROTECT 100** have been developed with a particular consideration to their compatibility with sensitive materials and protection against corrosion and discoloration.

# NOSOPROTECT®

## Highly concentrated mycobactericidal instrument disinfectant

NOSOPROTECT is a highly concentrated mycobactericidal instrument disinfectant combining excellent cleaning and disinfection efficiency. It has a broad spectrum of antimicrobial activity (including tuberculosis and mycobacteria) and effectively removes organic residues such as blood, lipids, polysaccharides, etc.

Its specific formula is perfectly adapted to heat-resistant and heat-sensitive materials. It can be used on any type of surgical instrument (scalpels, curettes, forceps, scissors …) or medical instrument (speculum, mirrors, stethoscope, etc.). It protects instruments from corrosion and discoloration.

It can be used in ultrasonic baths or immersion baths.


## Properties

- Very economical: 0,25 - 1% dilution
- Effectively removes organic residues
- Used in immersion or ultrasonic baths
- Prevents corrosion and instrument discoloration
- Fully compatible even with the most sensitive materials
- Bactericidal, fungicidal, tuberculocidal, mycobactericidal
- Virucidal (HBV, HIV, HCV, Herpes, Vaccinia, BVDV, Influenza, Ebola, Coronavirus...)
- Does not contain phenols, aldehydes, chlore or EDTA

## Disinfecting properties

| ACTIVITY SPECTRUM | STANDARD | STRAINS | DOSAGE ml/l - % | CONTACT TIME |
|---|---|---|---|---|
| BACTERICIDAL* (Dirty conditions) | EN 13727 | Pseudomonas aeruginosa Staphylococcus aureus Enterococcus hirae | 2,5 ml/l - 0.25% | 5 Min. |
| FUNGICIDAL (Dirty conditions) | EN 13624 | Candida Albicans | 2,5 ml/l - 0.25% | 5 Min. |
| VIRUCIDAL (Dirty conditions) | DVV(1)/RKI(2) 2014 | BVDV, Vaccinia, HBV, HIV, HCV, Ebola, Herpes, Influenza H1N1, H5N1, Coronavirus | 10 ml/l - 1% | 15 Min. |
| | | | 7,5 ml/l - 0.75% | 30 Min. |
| TUBERCULOCIDAL (Dirty conditions) | EN 14348 | Mycobacterium Terrae (Surrogate M. tuberculosis) | 20 ml/l - 2% | 15 Min. |
| | | | 10 ml/l - 1% | 60 Min. |
| MYCOBACTERICIDAL (Dirty conditions) | EN 14348 | Mycobacterium Terrae Mycobacterium Avium | 10 ml/l - 1% | 60 Min. |

* Including all the antibiotic resistant strains as MRSA, Klebsiella pneumoniae, Escherichia coli, streptococcus pneumoniae, etc.

1) DVV: Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten (German Association for the Control of Virus Diseases)

2) RKI: Robert Koch Institute - German Federal Health Authority

## Certifications

- CE mark according to the medical devices Directive (Directive 93/42/EEC)
- Medical device class IIb

## Packaging

- 5 litre canister (Ref. 20012)
- Dosing pump for 5 litre canister (Ref. 20023)

## Physical properties

| | |
|---|---|
| Appearance: | Transparent solution |
| Density: | 0.99 g/cm$^3$ at 20˚C |
| pH: | 12.0-12.8 at 20˚C |
| pH (1%): | 9.5-10.5 at 20˚C |
| Odour: | Neutral |
| Storage: | 5˚C - 35˚C |
| Stability: | 3 Years |
| Biodegradability: | according to OCDE 301D |

## Ultrasonic bath

NOSOPROTECT can be used in all common types of ultrasonic baths.

## Compatibility

NOSOPROTECT is compatible with most materials such as stainless steel, aluminum, glass, ceramics, hard plastics, ebonite, etc.

NOSOPROTECT is not compatible with disinfecting preparations containing aldehydes.

## Composition

N-(3-aminopropyl)-N-dodecylpropano-1,3-diamine, didecyl-dimethyl ammonium chloride, non-ionic surfactants <5%, isopropyl alcohol, corrosion inhibitor, anti-foaming agent, excipients.

# NOSOPROTECT 100®

## Foaming disinfectant spray for instrument pre-treatment



NOSOPROTECT 100 is a disinfecting foaming spray with a high detergency efficacy for the rapid pre-disinfection of surgical instruments immediately after use.

NOSOPROTECT 100 keeps the instruments moist, protects from corrosion and avoids organic residues deposits such as blood or proteins from drying.

It makes the reprocessing of instruments significantly safer, easier, and reduces the risk of infection between the operating room and the Central Sterile Service Department.

NOSOPROTECT 100 contains a complex of highly stabilized enzymes, surfactants, amines and corrosion inhibitors. This specific formulation has an increased efficiency while protecting sensitive materials.

NOSOPROTECT 100 does not contain alcohol, quaternary ammonium compounds (QAC), phenols, aldehydes, chlorine, EDTA, fragrances or colorants.

## Properties

- Ready-to-use sprayable foaming solution
- High efficiency cleaning and disinfection
- Keeps the instruments moisted
- Protects from corrosion and instrument discoloration
- Bactericidal, fungicidal, tuberculocidal, mycobactericidal
- Virucidal (HBV, HIV, HCV, Herpes, Vaccinia, BVDV, Influenza, Ebola, Coronavirus)
- Fully compatible even with sensitive materials

## Disinfecting properties

| ACTIVITY SPECTRUM | STANDARD | STRAINS | CONTACT TIME |
|---|---|---|---|
| **BACTERICIDAL*** (Dirty conditions) | EN 13727 | Pseudomonas aeruginosa Staphylococcus aureus Enterococcus hirae | 5 Min. |
| **FUNGICIDAL** (Dirty conditions) | EN 13624 | Candida Albicans | 5 Min. |
| **VIRUCIDAL** (Dirty conditions) | DVV(1)/RKI(2) 2014 | BVDV, Vaccinia, HBV, HIV, HCV, Ebola, Herpes, Influenza H1N1, H5N1, Coronavirus | 2 Min. |
| **TUBERCULOCIDAL** (Dirty conditions) | EN 14348 | Mycobacterium Terrae (Surrogate. M. tuberculosis) | 15 Min. |
| **MYCOBACTERICIDAL** (Dirty conditions) | EN 14348 | Mycobacterium Terrae Mycobacterium Avium | 15 Min. |

* Including all the antibiotic resistant strains as MRSA, Klebsiella pneumoniae, Escherichia coli, streptococcus pneumoniae, etc.

1) DVV: Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten (German Association for the Control of Virus Diseases)

2) RKI: Robert Koch Institute - German Federal Health Authority


## Packaging

- One litre bottle with spray (Ref. 20034)
- 5 litre refill canister (Ref. 20008)

## Physical properties

| | |
|---|---|
| Appearance: | Transparent foaming solution |
| Density: | 0.99 g/cm$^3$ at 20˚C |
| pH: | 9.5-10.5 at 20˚C |
| Odour: | Neutral |
| Storage: | 5˚C - 35˚C |
| Stability: | 3 Years |
| Biodegradability: | According to OCDE 301D |

## Compatibility

NOSOPROTECT 100 is compatible with most materials such as stainless steel, aluminium, glass, ceramics, hard plastics, rubber, plexiglass, polycarbonate, ebonite, etc.

NOSOPROTECT 100 is not compatible with disinfecting preparations containing aldehydes.

## Composition

Enzymes (protease, lipase, amylase), N-(3-aminopropyl)-N-dodecylpropano-1,3-diamine, non-ionic surfactants <5%, corrosion inhibitor, wetting agent, excipients.

## Certifications

- CE mark according to the medical devices Directive (Directive 93/42/EEC)
- Medical device class IIb



**NOSOPROTECT 100** is manufactured in the EU. **MEDALKAN** satisfies the requirements of **ISO 9001:2015** for quality management system and the requirements of **ISO 13485:2016** for the design and manufacture of medical devices.

# Instrument cleaning
## Manual and automated reprocessing

Proper instrument cleaning is a critical step of instrument reprocessing. This task has to be taken very carefully by the competent personnel within the Central Sterile Supply Department (CSSD) of any healthcare facility.

Proper cleaning and disinfection processes significantly reduce cross-contamination risks between medical devices & patients thus reducing nosocomial infections.

CSSD's use two main methods regarding medical and surgical instrument cleaning:

1. In immersion bath / by conventional hand washing
2. In automatic washer

In both cases, the use of an appropriate detergent is mandatory.

In immersion bath, an enzymatic solution is highly recommended in order to remove organic deposits as proteins, fats, starch and blood residues. The efficiency of an enzymatic detergent depends on the stability of the enzymes which has to be taken into consideration before purchase.

We have chosen the best available quality of enzymes on the market for our enzymatic cleaners **NOSOZYM** and **NOSOZYM 6 PLUS**. Highly stabilized, their activity last longer than any other.

In automatic washer, alkaline pH solutions are preferred to dissolve organic residues especially proteins and fats. Our alkaline detergent **NOSOCLEAN** has been developed with alkaline agents, specific surfactants and a new generation of protease for a powerful efficiency. Afterwards, we recommend the use of **CITRALKAN** or **NEUTRALKAN**, acidic neutralizing agents to remove alkaline residues and scale followed by the use of **NOSOCLEAR**, rinse-aid for a spotless finish and fast drying. The combination of those products ensures optimum results and helps to maintain the good condition of instruments and washer.

Medical and surgical instruments represent a large investment to any healthcare facility.
For this reason, each MEDALKAN product has been developed with a particular consideration in order to protect instruments and equipment from corrosion.

For optimum results and to ensure full compatibility between chemicals, MEDALKAN strongly recommends the use of the complete range of especially formulated reprocessing products at every step:

- **NOSOCLEAN** for a high performance and safe cleaning
- **CITRALKAN** or **NEUTRALKAN** for the removal of alkaline residues and scale
- **NOSOCLEAR** for a spotless finish and extra fast drying

# NOSOCLEAN ®

## Alkaline detergent for the reprocessing of surgical instruments and equipment



NOSOCLEAN is a highly concentrated and efficient alkaline detergent especially formulated for the cleaning of surgical instruments, medical equipment, ophtalmological instruments, anesthetic and endoscopic equipment, laboratory glassware and similar applications.

Formulated with alkaline agents, surfactants, highly stabilized enzymes and powerful corrosion inhibitors, NOSOCLEAN makes the dissolution of organic residues such as fat and protein deposits easier while effectively contributing to biofilm removal.

NOSOCLEAN is compatible with heat-resistant and heat-sensitive instruments. NOSOCLEAN has been specially developed and gives excellent cleaning results in washers from all major brands. It is also very efficient in ultrasonic baths or immersion baths.


### Properties

- Drastically efficient due to the specific combination of alkaline agents, surfactants and new generation of stabilized enzymes
- Does not leave any residues
- Contributes to the removal of biofilm
- Follows the guidelines of the Robert Koch Institute (RKI) concerning the decontamination of surgical instruments from prions (Creutzfeldt-Jacob disease).
- Can be used in soft or hard water
- Does not foam, prevents corrosion and instrument discoloration
- Compatible with heat-sensitive and heat-resistant instruments

### Composition

< 5% non ionic and anionic surfactants, enzymes, chelating agent, corrosion inhibitor, pH regulator

### Compatibility

NOSOCLEAN is compatible with most materials such as stainless steel, glass, ceramics, hard plastics, ebonite, etc. Material compatibility with sensitive materials should always be checked before use.

### Certifications

- CE mark according to the medical device Regulation (MDR) (Regulation 2017/745)
- Medical device class I

### Packaging

- 5 litre canister (Ref. 20026)
- 10 litre canister (Ref. 20027)
- Dosing pump for 5 litre canister (Ref. 20023)

### Physical properties

| | |
|---|---|
| Appearance: | Transparent solution |
| Density: | 1.02 g/cm$^3$ at 20˚C |
| pH: | 10.00-10.50 at 20˚C |
| pH (1% in deionised water): | 10,50-10.80 at 20˚C |
| Viscosity: | <50 mPas at 20˚C |
| Storage: | 5˚C - 35˚C |
| Stability: | 3 Years |
| Biodegradability: | According to OCDE 301D |

### Recommended dosage table

| CLEANING METHOD | RECOMMENDED DOSAGE (%) * | RECOMMENDED DOSAGE (ml/l) * | WATER TEMP. (°C) | CONTACT TIME |
|---|---|---|---|---|
| IN IMMERSION BATH | 0,4% - 2% | 4 ml/l - 20 ml/l | 20 - 60 °C | 5 - 15 min |
| IN ULTRASONIC BATH | 0,4% - 2% | 4 ml/l - 20 ml/l | 20 - 60 °C | 5 - 10 min |
| IN AUTOMATED REPROCESSOR | 0,1% - 1% | 1 ml/l - 10 ml/l | 55 - 95 °C | 5 - 20 min ** |
| | 0,5% (standard doage) | 5 ml/l | 60 °C | 5 min |

* Always adjust the dosage and contact time depending on the degree of contamination and cleaning method you follow. Recommended dosages can be adjusted or exceeded according to the quality and temperature of the water and the type of washer used.

** Depending on the recommendations of the washer's manufacturer.



**NOSOCLEAN** is manufactured in the EU. **MEDALKAN** satisfies the requirements of **ISO 9001:2015** for quality management system and the requirements of **ISO 13485:2016** for the design and manufacture of medical devices.

# NEUTRALKAN ®

## Acidic neutralizing agent & Instrument renovator

# CITRALKAN®

## Acidic neutralizing agent for the reprocessing of instruments

NEUTRALKAN and CITRALKAN are acidic detergents. They remove limescale, rust stains and mineral deposits off the instruments as well as the inside walls of washer disinfectors.

They can be used in automatic washers, washer disinfectors or other instrument reprocessing equipment as a neutralising agent of alkaline residues for surgical instruments and glassware.

NEUTRALKAN can also be used in immersion bath as a powerful instrument renovator. NEUTRALKAN will remove rust stains and restore the initial brilliance of degraded or discoloured instruments.


| | NEUTRALKAN | CITRALKAN |
|---|---|---|
| **PROPERTIES** | ■ Restores the initial brilliance of degraded or discoloured instruments<br>■ Removes alkaline residues, mineral scale and rust stains<br>■ Restores stainless steel surface finish<br>■ Keeps the washer disinfector's chamber clean and shiny<br>■ Very economical: 0.05% to 0.4% dilution<br>■ Does not contain any surfactants<br>■ Prevents corrosion and instruments discoloration | ■ Removes alkaline residues, mineral scale and rust stains<br>■ Acidic pre-cleaning of instruments and laboratory glassware<br>■ Keeps the washer disinfector's chamber clean and shiny<br>■ Based on organic acids<br>■ Very economical: 0,1% to 0,2% dilution<br>■ Does not contain any surfactants, prevents corrosion and instrument discoloration |
| **PHYSICAL PROPERTIES** | ■ Appearance: Transparent solution<br>■ Density: 1.50 g/cm$^3$ at 20˚C<br>■ pH (0,5 - 4 ml/l.): <2 at 20˚C<br>■ Viscosity: <20 mPas at 20˚C<br>■ Storage: 5˚C - 35˚C<br>■ Stability: 3 Years<br>■ Biodegradability: According to OCDE 301D | ■ Appearance: Transparent solution<br>■ Density: 1,15 g/cm$^3$ at 20˚C<br>■ pH (1 - 2 ml/l.): <3 at 20˚C<br>■ Viscosity: <10 mPas at 20˚C<br>■ Storage: 5˚ - 35˚C<br>■ Stability: 3 Years<br>■ Biodegradability: According to OCDE 301D |
| **PACKAGING** | ■ 5 litre canister (Ref. 20028)<br>■ 10 litre canister (Ref. 20029) | ■ 5 litre canister (Ref. 20076)<br>■ 10 litre canister (Ref. 20077) |
| **COMPOSITION** | Citric acid, Phosphoric acid > 50% | Citric acid ≥ 40%, Corrosion inhibitors |
| **DOSAGE** | ■ In washer disinfectors at a dilution from 0,5 ml/l. (0,05%) to 4 ml/l. (0,4%).<br>■ In immersion bath at a dilution from 20 ml/l. (2%) to 40 ml/l. (4%).<br>The dilution rate depends on the quality and temperature of the water. The solution has to be rinsed off after use. The use of deionized water should be preferred. | ■ In washer disinfectors at a dilution from 1 ml/l. (0,1%) to 2 ml/l. (0,2%).<br>The dilution rate depends on the quality and temperature of the water. The solution has to be rinsed off after use. The use of deionized water should be preferred. |
| **COMPATIBILITY** | Compatible with most materials like stainless steel, glass, ceramics and acid resistant materials.<br>Material compatibility with sensitive materials should always be checked before use | |
| **CERTIFICATIONS** | CE mark according to the medical device Regulation (MDR) (Regulation 2017/745)<br>Medical device class I | |



**NEUTRALKAN** and **CITRALKAN** are manufactured in the EU. **MEDALKAN** satisfies the requirements of **ISO 9001:2015** for quality management system and the requirements of **ISO 13485:2016** for the design and manufacture of medical devices.

# NOSOCLEAR ®

## Rinse aid for the automated reprocessing of medical and surgical instruments



NOSOCLEAR is a concentrated rinse aid especially formulated for the fast and spotless drying of surgical instruments, glassware, and other sensitive medical devices.

NOSOCLEAR gives excellent results in all types of automatic washers and washer-disinfectors.

NOSOCLEAR reduces the surface tension of the water on the instruments allowing them to dry quickly without leaving any traces.

NOSOCLEAR is compatible with stainless steel instruments, ophtalmological instruments, anesthetic equipment, laboratory glassware, plastics and hard rubbers.


### Properties

- Drastically shortens drying time
- Leaves the instruments filmless and spotfree
- Very economical: 0,01% to 0,03% dilution
- Can be used in soft or hard water
- Does not foam, prevents corrosion and instrument discoloration
- Compatible with heat-resistant and heat-sensitive instruments

### Composition

Non ionic surfactants 15% - 20%, phosphonates, corrosion inhibitor, pH regulator, excipients.

### Compatibility

NOSOCLEAR is compatible with most materials such as stainless steel, aluminum, glass, ceramics, hard plastics, ebonite, etc.
*Material compatibility with sensitive materials should always be checked before use.*

### Certifications

- CE mark according to the medical device Regulation (MDR) (Regulation 2017/745)
- Medical device class I
- NOSOCLEAR has been tested according to ISO 10993-1 and is not toxic

### Packaging

- 5 litre canister (Ref. 20030)
- 10 litre canister (Ref. 20031)

### Physical properties

| | |
|---|---|
| Appearance: | Transparent yellow solution |
| Density: | 1.02 g/cm$^3$ at 20˚C |
| pH: | 6.0-7.0 at 20˚C |
| pH (0,2-0,8ml/l): | 7.0-8.0 (neutral) at 20˚C |
| Viscosity: | <50 mPas at 20˚C |
| Storage: | 5˚C - 35˚C |
| Stability: | 3 Years |
| Biodegradability: | According to OCDE 301D |

### Dosage

NOSOCLEAR is to be used in washer disinfectors during the rinsing cycle at a dilution from 0,1 ml/l. (0,01%) to 0,3 ml/l. (0,03%).

The dilution rate depends on the quality and temperature of the rinse water. For best results, the use of deionised water is prefered.



**NOSOCLEAR** is manufactured in the EU. **MEDALKAN** satisfies the requirements of **ISO 9001:2015** for quality management system and the requirements of **ISO 13485:2016** for the design and manufacture of medical devices.

# A complete range of detergents for automated bedpan reprocessing

Cleaning and disinfection of bedpans and other care utensils have to be achieved with the most possible care.

A strict procedure is mandatory to avoid any cross-contamination from the patient room to the CSSD.

Adapted detergents especially developed for a use in automated bedpan-washers significantly reduce the infectious risk by potential pathogens contaminating human waste.

For this reason, MEDALKAN has designed two complementary chemicals for a specific use in bedpan washer-disinfectors:

1. Cleaning phase: NOSOMATIC SK1 as a powerful alkaline detergent able to remove the most stubborn organic residues while maintaining the internal surfaces of washers clean

2. Rinsing phase: NOSOMATIC SK2 as an acidic descaler and rinse aid which prevents the formation of lime scale, protects boiler and avoids water spots while accelerating the drying process.

For optimum results and to ensure full compatibility between chemicals, MEDALKAN strongly recommends the use of the complete range of especially formulated reprocessing products at every stage:

- **NOSOMATIC SK1** for a high performance and safe cleaning
- **NOSOMATIC SK2** for the removal of lime scale and a spotless finish with extra fast drying

# NOSOMATIC® SK1

## Alkaline detergent for bedpan washer-disinfectors

NOSOMATIC SK1 is a highly concentrated and efficient alkaline detergent especially formulated for the automated cleaning of bedpans, urine bottles, glassware, commode pots and other utensils.

NOSOMATIC SK1 dissolves and removes stubborn organic residues such as urine and human excrements while maintaining the internal surfaces of washers clean.

Non foaming, it is perfectly adapted to automated washers.

Formulated with powerful corrosion inhibitors, NOSOMATIC SK1 protects glass bottles, stainless steel, bedpans and other specific containers from corrosion and discoloration.


### Properties

- Drastically efficient due to the specific combination of alkaline and sequestring agents
- Can be used in soft or hard water
- Does not foam
- Prevents corrosion and discoloration
- Appropriate for heat-sensitive utensils
- Keeps the chamber of washers perfectly clean

### Composition

Sequestring agents, corrosion inhibitors, pH regulator

### Compatibility

NOSOMATIC SK1 is compatible with most materials such as stainless steel, glass, plastics, ceramics, ebonite, etc.

Material compatibility with sensitive materials should always be checked before use.

### Certifications

- CE mark according to the medical devices MDR Regulation (EU) 2017/745
- Medical device class I

### Packaging

- 5 litre canister (Ref. 20080)
- 10 litre canister (Ref. 20081)

### Physical properties

| | |
|---|---|
| Appearance: | Transparent solution |
| Density: | 1.2 g/cm$^3$ at 20˚C |
| pH: | 11.00 at 20˚C |
| pH (1% in deionised water): | 10.70-11.00 at 20˚C |
| Viscosity: | <50 mPas at 20˚C |
| Storage: | 5˚C - 35˚C |
| Stability: | 3 Years |
| Biodegradability: | According to OCDE 301D |

### Dosage

Set up the washer for a dilution of 0,1% (1ml/l) to 0,3% (3 ml/l). The dosing is achieved through the washer's interface. Follow the washer manufacturer's instructions. Always adjust the dosage and contact time depending on the degree of soiling and water hardness. For best results, the use of deionised water is prefered.

NOSOMATIC SK2 - Acidic descaler and rinse aid, should be used during the rinsing cycle to complete the reprocessing.





**NOSOMATIC SK1** is manufactured in the EU. **MEDALKAN** satisfies the requirements of **ISO 9001:2015** for quality management system and the requirements of **ISO 13485:2016** for the design and manufacture of medical devices.

# NOSOMATIC® SK2

## Acidic descaler & rinse aid for bedpan washer-disinfectors

NOSOMATIC SK2 is an acidic descaler & rinse aid specially formulated for use in bedpan washer-disinfectors.

It is used for the descaling and drying of bedpans, urine bottles, commode pots and other disposal receptacles and utensils.

NOSOMATIC SK2 accelerates the drying process while preventing the formation of water spots.

In washers with built-in steam generators, NOSOMATIC SK2 provides reliable protection against the formation of lime scale in boiler, pipes and jet nozzles even at high degrees of water hardness.


### Properties

- Rapid and stain-free drying
- Appropriate for heat-sensitive ustensils
- Protects the boiler and chamber from lime scale deposits
- Can be used in soft or hard water
- Prevents the formation of scale and water spots
- Pleasant fresh odour

### Composition

Anionic and non-ionic surfactants, organic acid, corrosion inhibitors, pH regulator, fragrance

### Compatibility

NOSOMATIC SK2 is compatible with most materials such as stainless steel, glass, plastics, ceramics, ebonite, etc.

Material compatibility with sensitive materials should always be checked before use.

### Certifications

- CE mark according to the medical devices MDR Regulation (EU) 2017/745
- Medical device class I

### Packaging

- 5 litre canister (Ref. 20083)
- 10 litre canister (Ref. 20084)

### Physical properties

| | |
|---|---|
| Appearance: | Transparent solution |
| Density: | 1.1 g/cm$^3$ at 20˚C |
| pH: | 2.50-3.00 at 20˚C |
| pH (1% in deionised water): | 2.50-3.00 at 20˚C |
| Odour: | Fresh scent |
| Viscosity: | <50 mPas at 20˚C |
| Storage: | 5˚C - 35˚C |
| Stability: | 3 Years |
| Biodegradability: | According to OCDE 301D |

### Dosage

Set up the washer for a dilution of 0,05% (0,5 ml/l) to 0,15% (1,5 ml/l). The dosing is achieved through the washer's interface. Follow the washer manufacturer's instructions. Always adjust the dosage and contact time depending on the degree of soiling, water hardness. For best results, the use of deionised water is prefered.

Medalkan
HYGIENE & DISINFECTION

# MEDALKAN HOSPITALS AND CLINICS PRODUCT CHARACTERISTICS

| PRODUCT OVERWIEW | FIELD OF ACTIVITY | | | | MATERIAL COMPATIBILITY | | | | | | | | | OTHER COMPATIBILITY | | | | SPECTRUM OF ACTIVITY | | | | | | | PH | | | PACKAGING | RECOMMENDED DOSAGE RANGE (%) | MEDICAL DEVICE CLASS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | CLEANING | DISINFECTION | NEUTRALISING | RINSING | ALUMINIUM | STAINLESS STEEL | CHROME | PEXIGLASS | CERAMICS | HARD PLASTICS | EBONITE | LEATHER | RUBBER | ULTRASONIC BATHS | WASHER DISINFECTORS | BEDPAN W-D | ENDOSCOPES | BACTERICIDAL | FUNGICIDAL * | VIRUCIDAL** | NON ENVELOPED VIRUS | MYCOBACTERICIDAL | TUBERCULOCIDAL | SPORICIDAL | ALKALINE | NEUTRAL | ACIDIC | | | |
| **SURFACE CLEANING AND DISINFECTION** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| NOSOSEPT 100 | x | x | | | x | x | x | | x | x | x | | | | | | | x | x | x | | x | x | | x | | | SPRAY 1L CANISTER 5 L | READY TO USE | IIa |
| NOSOFAST TB | x | x | | | x | x | x | x | x | x | x | x | x | | | | | x | x | x | | x | x | | x | | | SPRAY 1L CANISTER 5 L | READY TO USE | IIa |
| NOSOFLOOR | x | x | | | x | x | x | | x | x | x | | | | | | | x | x | x | | x | x | | x | | | 5 L | 0,25% TO 1% | IIa |
| **INSTRUMENT CLEANING & DISINFECTION** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| NOSOPROTECT | x | x | | | x | x | x | | x | x | x | | | x | | | | x | x | x | | x | x | | x | | | 5 LITRE | 0,25% TO 1% | IIb |
| NOSOPROTECT 100 | x | x | | | x | x | x | | x | x | x | | | | | | | x | x | x | | x | x | | x | | | SPRAY 1L CANISTER 5 L | READY TO USE | IIb |
| **ENDOSCOPE & INSTRUMENT CLEANING & HIGH LEVEL DISINFECTION** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| NOSOZYM | x | | | | x | x | x | x | x | x | x | x | x | x | x | | x | | | | | | | | | | x | | 5 LITRE | up to 0,5% | I |
| NOSOZYM 6 PLUS | x | | | | x | x | x | x | x | x | x | x | x | x | x | | x | | | | | | | | | | x | | 5 LITRE | up to 0,5% | I |
| NOSOCID PAA | | x | | | x | x | x | x | x | x | x | | x | | | | x | x | x | x | x | x | x | x | | | x | 5 LITRE | READY TO USE | IIb |
| **INSTRUMENT AUTOMATED REPROCESSNG** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| NOSOCLEAN | x | | | | x | x | x | x | x | x | x | | x | x | x | | | | | | | | | | x | | | 5 LITRE | 0,4% TO 2% | I |
| CITRALKAN | x | | x | | x | x | x | x | x | x | | | x | | x | | | | | | | | | | | | x | 5 LITRE | 0,1% TO 0,2% | I |
| NEUTRALKAN | | | x | | x | x | x | x | x | x | | | x | | x | | | | | | | | | | | | x | 5 LITRE | 0,05% TO 0,4% | I |
| NOSOCLEAR | | | | x | x | x | x | x | x | x | x | | x | | x | | | | | | | | | | | x | | 5 LITRE | 0,01% TO 0,03% | I |
| **BEDPAN REPROCESSNG DETERGENTS** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| NOSOMATIC SK1 | x | | | | x | x | x | x | x | x | x | | x | | x | x | | | | | | | | | x | | | 5 LITRE | 0,1% TO 0,3% | I |
| NOSOMATIC SK2 | | | x | x | x | x | x | x | x | x | x | | x | | x | x | | | | | | | | | | | x | 5 LITRE | 0,05% TO 0,15% | I |

** Includes yeasts and if applicable molds / Refer to the Product's Data Sheet (PDS) for further details
* Tested according to DVV/RKI recommendation and/or EN 14476 / Refer to the Product's Data Sheet (PDS) for further details

REF: BR4EN 05/04/2024

Your distributor



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