Germo® S.P.A.
Sede Legale Stabilimento e Uffici: 20032 CORMANO (Milano) Via Giotto, 19/21
Telefono +39-0266301938 r.a. - Telefax +39-0266301939
E-mail: info@germodis.com www.germo.it
Capitale Sociale € 156.000,00 interamente versato - R.E.A. 497966 Cod. Fisc. e Part. IVA 00772350153 - Iscr. 125750 R.I. Canc. Trib. MI

GERMOCID LINE - TECHNICAL DATASHEET

GERMOCID INSTRUMENTS

GERMOCID INSTRUMENTS is a Medical Device class IIb in compliance with Directive 93/42/EEC.
GERMOCID INSTRUMENTS is a concentrated solution that performs a rapid and efficacious cleansing and disinfectant action before sterilization. GERMOCID INSTRUMENTS is used on invasive surgical instruments contaminated with organic material (blood, saliva and biological exudates) and does not require mechanical action to complete the cleansing process.
GERMOCID INSTRUMENTS is a specific product for decontamination, cleaning and high-level disinfection of invasive surgical instruments; the formulation is active against Gram-positive and Gram-negative bacteria, mycobacteria, fungi and viruses (Adenovirus, HIV, HBV, HCV). Free of aldehydes, colorants, toxic or health-damaging substances, GERMOCID INSTRUMENTS combines a high antimicrobial efficacy and an excellent cleansing action thanks to the synergic action of the active ingredients and the surfactants in the formula. GERMOCID INSTRUMENTS performs the maximum biocidal product activity with the necessary compatibility with the materials, also being effective in the presence of hard water and organic dirt. Specific corrosion inhibitors guarantee the absolute compatibility of the product with the most used materials in dental and hospital.

INSTRUCTIONS FOR USE

GERMOCID INSTRUMENTS is used diluted in water in different concentrations depending on the disinfection you want to obtain. To prepare the solution, use the measuring cup if supplied. Immerse the instruments to be used for the chosen contact time. Rinse thoroughly with water before use. The solution remains stable for a week. In case of frequent use and with particularly contaminated or dirty instruments it is advisable to replace the solution every day. GERMOCID INSTRUMENTS can also be used in ultrasound equipment. For professional use.
Bactericidal activity: use a concentration of 5-10% for a contact time of 15'.
Yeasticidal activity: use a concentration of 1-10% for a contact time of 15'.
Fungicidal activity: use a concentration of 15% for a contact time of 15'.
Mycobactericidal activity: use a concentration of 10% for a contact time of 60'.
Virucidal activity: vs Adenovirus use a concentration of 1% for a contact time of 60', vs HIV-HBV-HCV use a concentration of 15% for a contact time of 60'.

PACKAGING

Internal Code:	Primary packaging:	Secondary packaging:
F101	1000 ml bottle	Box containing 6 bottles
F105	5000 ml canister	Box containing 4 canisters

Barcode	ITF	Box size (mm)	Pallet composition
8009110029804	08009110029804	265 w x 175 d x 273 h	80 ctn (4 floors x 20)
8009110025783	-	381 w x 274 d x 290 h	32 ctn (4 floors x 8)

All primary packaging is made of high polyethylene density (HDPE) according to the specifications provided by the Pharmacopoeia. This material does not contain allergenics and is perfectly compatible with all components of the formulation.

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COMPOSITION

100,0 g of product contain:
Benzalkonium chloride 10,0 g; O-phenylphenol 1,0 g; coformulants; depurated water q.s. to 100,0 g.

PRODUCT FORM

Teal blue liquid.

ACTIVITY

Thanks to its specific formulation, GERMOCID INSTRUMENTS has a large spectrum of action against many pathogenic microorganisms such as Gram-positive and Gram-negative bacteria, fungi, mycobacteria and viruses.

Norm	Activity	Active concentration	Contact Time
EN13727 EN14561	Bactericidal	10% 5%	15 minutes 15 minutes
EN13624 EN14562	Yeasticidal	10% 1%	15 minutes 15 minutes
EN14562	Fungicidal	15%	15 minutes
EN14348 EN14563	Mycobactericidal	10% 10%	60 minutes 60 minutes
EN14476	Virucidal Adenovirus HIV, HCV, HBV	 1% 15%	 60 minutes 60 minutes

WARNINGS

In case of frequent use and with particularly contaminated or dirty instruments it is advisable to replace the solution every day.

VALIDITY

3 years. The indicated period of validity refers to the product stored in its container and properly used and stored.

HOW TO STORAGE

Store in a cool, dry place, away from heat sources.

QUALITY CONTROL

The components (raw materials, containers, labels, etc.) and the processing steps of each lot are regularly and carefully checked internally following the procedures of the Organization Quality Management System certified UNI EN ISO 9001 and UNI EN ISO 13485.

AUTHORIZATIONS

Medical Device CE 0546 class IIb in compliance with Directive 93/42/ECC as amended by Directive 2007/47/EEC.

CONFIDENTIAL INFORMATION FOR PROFESSIONAL USERS