

## GERMOCID LINE - TECHNICAL DATASHEET

### GERMOCID GLUTACARE

GERMOCID GLUTACARE is a Medical Device CE 0546 class IIb in compliance with Directive 93/42/EEC.

GERMOCID GLUTACARE is a ready-to-use solution for high-level disinfection of invasive medical devices. GERMOCID GLUTACARE is used for the treatment of thermolable and non-autoclavable medical equipment (e.g. ultrasonic transducers, pulse oximeter probes, stethoscopic and endoscopic probes, ECG devices, incubators, equipment for blood pressure measure, radiologic instruments, monitors etc). GERMOCID GLUTACARE has a high efficiency, and it is quick and safe. Glutaraldehyde in combination with O-phenylphenol and Isopropyl alcohol provides a broad spectrum of action against pathogens such as Gram-positive and Gram-negative bacteria, Mycobacterium tuberculosis, fungi, spores and viruses (Adenovirus, HIV, HBV and HCV). Thanks to its coformulants also it has a strong detergent power. GERMOCID GLUTACARE provides a rapid disinfection and allows a fast reuse of instruments and it respects the most sensitive parts of the treated instruments (optical fibers, adhesives, plastics, rubbers and metals) and does not have a corrosive and oxidizing action.



#### PROPERTIES

GERMOCID GLUTACARE is used for high-level disinfection and aseptic conservation of invasive surgical instruments (for both hospital and dental ones). The solution can also be used in ultrasound equipment. For professional use.

#### INSTRUCTIONS FOR USE

It is advised to precede the treatment with a suitable cleansing. *GERMOCID GLUTACARE is used as it is for instruments disinfection.* Immerse the instruments in the solution for 5 minutes to have an antibacterial action, 15 minutes vs fungi and viruses, 60 minutes vs Mycobacterium tuberculosis and for 4 hours for a sporicidal action. Complete the processes with an accurate rinsing phase with sterile water. The 2% Glutaraldehyde solutions have been shown to maintain disinfectant properties in the presence of contamination with organic material and microbial load for a period of 14 days. Do not exceed the times indicated. The scientific literature also recommends repeated use in endoscope washing machines for a number of disinfection cycles not exceeding 30-40. *For an aseptic conservation immerse the disinfected instruments in a product solution diluted to 10% in water or alcohol until the time of use.* Rinse the instruments with sterile water before use. In case of a prolonged period in contact with the aqueous solution (more than 24 hrs), to preserve the metal parts it is necessary to add an antioxidant product to the solution. Avoid the simultaneous immersion of medical devices of different metal alloys or carbon steel for more than 24 hrs.

#### PACKAGING

Internal code:	Primary packaging:	Secondary packaging:
R506	1000 ml bottle	Box containing 12 bottles

Barcode	ITF	Box size (mm)	Pallet composition
8009110031111	089110031111	335 w x 253 d x 274 h	40 ctn (4 floors x 10)



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#### **COMPOSITION**

100,0 g of the product contain: Glutaraldehyde 2,0 g; O-phenylphenol 0,5 g; Isopropyl alcohol; coformulants; depurated water q.s. to 100,0 g.

#### **PRODUCT FORM**

Clear colorless liquid.

#### **ACTIVITY**

GERMOCID GLUTACARE is a ready-to-use solution for high-level disinfection against Gram-positive and Gram-negative bacteria, *Mycobacterium tuberculosis*, fungi, spores and viruses.

Norm	Activity	Contact time
EN13727-EN14561	Bactericidal	5 minutes
EN13624-EN14562	Fungicidal	15 minutes
EN14476	Virucidal (Adenovirus, HIV, HBV, HCV)	15 minutes
EN14348-E14563	Mycobactericidal (TBC)	60 minutes
EN13704	Sporicidal	4 hours

#### **WARNINGS**

Keep out of reach of children. Do not use with alkali. Dispose in accordance with the national regulation in relation to the composition of the product.

#### **VALIDITY**

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

#### **HOW TO STORAGE**

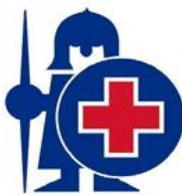
Store in a cool, dry place, away from heat sources.

#### **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/EEC as amended by Directive 2007/47/EEC.



**Germo<sup>®</sup>**  
S.p.A.

Capitale Sociale € 156.000,00 interamente versato - R.E.A. 497966 Cod. Fisc. e Part. IVA 00772350153 - Iscr. 125750 R.I. Canc. Trib. MI

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