

## INSTRUCTION FOR USE

### Medical Instrument Disinfectant; Glutaraldehyde 2 % with Activator



**PRODUCT NAME** : Medical Instrument Disinfectant:  
Glutaraldehyde 2 % with Activator

**TRADEMARK** : SANITAROSA™ GA ACT

**PRODUCT REF NO:** 6002

PACKING TYPE	ORDER NO
5 Liter HDPE Canister	436002025000

**INTENDED USE:** High-level disinfection and cold sterilization of medical devices, surgical equipment, endoscopic and thermosensitive equipment.

#### **PRODUCT SPECIFICATION**

Form	Liquid
Color	Light Yellowish
Odor	Aldehyde
pH @ 25°C	4.0±0.5
pH 25°C (After Activation)	8.0±0.5

#### **COMPOSITION**

Glutaraldehyde (2%), corrosion inhibitor and distilled water. Does not contain any acetate, borate, phosphate, detergent, and colorant.

#### **INDICATIONS**

Indicated for high-level disinfection and cold sterilization of endoscopes, surgical-medical and heat-sensitive equipment.

#### **CONTRAINDICATIONS**

- SANITAROSA™ GA ACT should NOT be used to sterilize reusable medical devices that are compatible with other available methods of sterilization that can be biologically monitored, e.g.: heat, ethylene oxide, or peroxide gas plasma.
- SANITAROSA™ GA ACT should not be used for sterilization of critical devices intended for single use (e.g.: catheters).
- SANITAROSA™ GA ACT should NOT be used to achieve high-level disinfection of a semi-critical device when sterilization is practical.
- SANITAROSA™ GA ACT should not be used for sterilization of rigid endoscopes which device manufacturers indicate are compatible with sterilization processes that can be biologically monitored (e.g. steam, dry heat, ethylene oxide, hydrogen peroxide gas plasma).

## **PRECAUTIONS**

- Protective gloves (butyl rubber, nitrile rubber, polyethylene, or double-gloved latex), eye protection, face masks, and liquid-proof gowns should be worn when cleaning and sterilizing/disinfecting soiled devices and equipment.
- Contaminated, reusable medical devices **MUST BE THOROUGHLY CLEANED** prior to immersion in SANITAROSA™GA ACT Solution since residual contamination will decrease the effectiveness of the disinfectant.
- The user **MUST** adhere to the Instruction for Use since any modification will affect the safety and effectiveness of the disinfectant.

## **HOW TO USE**

**Pre-cleaning:** Wipe down the external surface of the surgical instrument with gauze or a cloth, to remove the mucous membrane, blood and filth that adhere to the external surface. Either moistened gauze or dry gauze is fine. After the outer surface of the instruments is wiped with a cloth, it must be treated with an enzymatic detergent (Ref no: 6160 GBL® WARECLEAN™ EC) before disinfection.

### **Activation:**

Add 125 ml of activator solution (Ref no: 6016 Rosa-Chem GA ACT) into 5 Liter glutaraldehyde disinfectant canister. Mix slowly. The mixed solution is ready for high-level disinfection.

### **Disinfection:**

Pour activated SANITAROSA™ GA ACT disinfectant solution into the disinfection container. Pre-cleaned devices with enzymatic detergent (Ref no: 6160 GBL® WARECLEAN™ EC) are immersed into the container so that all the surfaces and holes will contact the solution. Wait according to the requested activity (contact times given below table). Rinse with sterile or distilled water. Keep the medical device as aseptically as possible until use. SANITAROSA™ GA ACT can be used up to 14 days.

### **Product Effectiveness Control with MEC Test Strips:**

After 14 days, if the disinfectant solution in the container will be checked with Rosa-Strip GA (REF No: 7001) and be found still active, the disinfectant solution can still be used up to 30 days. It is recommended to replace the solution in case of visible contamination and organic waste.

### **Directions for ROSA-STRIP GA**

Open the ROSA-STRIP GA Test Strips bottle and remove the test strip. Close the bottle. Completely immerse the indicator pad of the strip in glutaraldehyde solution. Remove after 2 seconds. Do not stir the glutaraldehyde solution with the strip. Do not shake the test strip to make it dry. Dry the test strip only by laying down the test strip on a paper towel. Compare the test strip reaction zone color with the color scale on the test strip bottle at 60 seconds. Do not read results past 60 seconds. Close the test strips' bottle caps immediately after use. After the test strips bottle once opened, use all test strips within 90 days. Discard unused test strips within 90 days. Store tightly closed test strip bottle between 15-30 °C and out of direct sunlight.



PASS



FAIL



FAIL



FAIL

### **DISINFECTANT/CONTAINER DISPOSAL INFORMATION**

Dispose of content/container in accordance with local/regional/national/international regulations.

For 5 Liter solution use just 125 g Ref no: 6128 Neutralizer for SANITAROSA GA. Pour the neutralizer to the container. Stir 10 minutes. After 10 minutes you can discharge safely the neutralized solution according to the waste disposal rules of your country. Neutralized solution is not harmful to the environment.

### MICROBIOLOGICAL EFFECT TABLE

Effect	Standard	Microorganism (with ATCC)	Contact Time
Bactericidal	EN 13727 / EN 14561	<i>Staphylococcus aureus</i> 6538 <i>Pseudomonas aeruginosa</i> 15442 <i>Enterococcus hirae</i> 10541	10 min.
Fungicidal	EN 13624 / EN 14562	<i>Candida albicans</i> 10231 <i>Aspergillus brasiliensis</i> 16404	10 min.
Mycobactericidal	EN 14563	<i>Mycobacterium terrae</i> 15755 <i>Mycobacterium avium</i> 15769	10 min.
Virucidal	EN 14476+ A1	<i>Adenovirus type 5, strain Adenoid</i> 75, ATCC VR-5 <i>Murine norovirus (MNV) strain</i> S99, RVB-651 <i>Poliovirus type 1, LSc-2ab</i>	10 min.
Sporicidal	AOAC	<i>Bacillus subtilis</i> 6633	3 hours

### WARNINGS AND POTENTIAL ADVERSE EFFECTS

**The product is for professional use only.**

**Danger.** Causes skin irritation. Causes serious eye damage. May cause respiratory irritation. Avoid breathing dust/fumes/gas/mist/vapor spray. Wear protective gloves/protective clothing/eye protection/face protection. Call a POISON CENTER or doctor/physician if you feel unwell. IF ON SKIN: Wash with plenty of soap and water. IF INHALED: Remove the person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove the contact lens if present and easy to do – continue rinsing. Store in a well-ventilated place. Keep the container tightly closed.

Glutaraldehyde is an irritant to the skin, eyes, and respiratory system. Skin contact may cause minor irritation with itching and slight local redness. Prolonged contact causes mild to moderate local redness and swelling. In concentrations less than 5% it is considered irritating to eyes, although higher concentrations can present a risk of serious damage to the eyes. These symptoms are generally temporary and should subside when the employee leaves the area of glutaraldehyde exposure. There is no evidence of adverse reproductive or carcinogenic health.

### STABILITY AND STORAGE

SANITAROSA™ GA ACT should be stored in its original sealed container in a well-ventilated area at 5°C-35°C, in the shade and away from direct sunlight.

Storage Temperature	Shelf Life	Usage Time After Opening the Cap
5/35 °C	2 years	3 months

## PACKAGING

Product	Packaging Type	Packaging Units
SANITAROSA™ GA ACT	HDPE Canister	5 Liter x 2

## ACCESSORIES

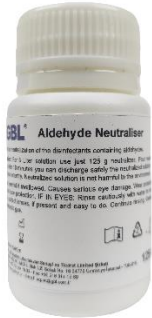
PRODUCT NAME	REF NO	ORDER NO	Packaging Type	Packaging Units
Glutaraldehyde Activator	6016	436016000125	HDPE; Bottle	125 ml x 108
Glutaraldehyde MEC* Test Strips	7001	457004070025	HDPE; Bottle	25 strips x 72
Neutralizer for SANITAROSA™ GA ACT	6219	436219000125	HDPE; Bottle	125 gr x 100

\*MEC: Minimum Effective Concentration

Neutralizer for  
SANITAROSA™ GA

Rosa-Chem GA

Ref no: 6219



Glutaraldehyde  
MEC Test Strips

ROSA-STRIP GA

Ref no: 7001



Glutaraldehyde  
Activator

Rosa-Chem  
GA ACT

Ref no: 6016



## LABEL SYMBOL KEYS



Catalog Number



Production  
Date



Storage  
Temperature



Manufacturer  
Information



Batch Code



Expiry Date



Refer to User  
Guide



Complies with European  
product regulations.  
1984: Notified body  
number.



Recycling  
Information



GHS05  
Corrosive



GHS07  
Harmful



Usage Time After  
Opening the Cap

## MANUFACTURER



GBL® Gül Biyoloji Laboratuvarı Sanayi ve Ticaret Anonim Şirketi

HQ: Serifali Mah. Hattat Sk. No:10 P.O.: 34775 Ümraniye İstanbul TÜRKİYE

Factory: Dudullu OSB Mah. İMES C Blok 305 Sk. No:16 P.O.: 34775 Ümraniye İstanbul TÜRKİYE

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