CANTEL

Via Laurentina 169
00071 POMEZIA (RM)
ITALY

PROTEAZONE
TECHNICAL DATA SHEET
MEDICAL DEVICE *Class II b*
ID CODE PAZ/CE/22

1. Medical Device Name

PROTEAZONE

2. Qualitative and Quantitative Composition

- Adazone	**< 0,1%**
- Multienzymatic mixture	**< 2,0%**
- Non-Ionic Surfactant	**< 30%**
- Co-formulants and purified water	

3. Product presentation

The product is a concentrated disinfectant and decontaminant solution of balanced, mycobactericidal, bactericidal, virucidal, fungicidal and surfactant formulation, synergised with Adazone. It is designed specifically for the elimination of microbial biofilm for invasive and non invasive medical devices. Disinfecting activity, which occurs as a result of synergism between the different components, is verified for mycobactericidal, bactericidal, virucidal, and fungicidal activity according to regulations CEN/TC 216 and EPA DIS-TSS07.

4. Microbiological Activity and Properties with compliance to UNI EN 14885: 2019 "Application of European standards for chemical disinfectants and antiseptics"

Mycobactericidal Activity UNI EN 14885: 2019

Method Used	**EN 14348 Mycobactericidal activity test for the medical area (IBL = 10^9 R ≥ 4 log, in clean and dirty condition)**
Strains Employed	*Mycobacterium smegmatis CIP 7326* *Mycobacterium terrae ATCC 15755* *Mycobacterium avium ATCC 15769*
Result	**Contact Time: 5'- Reduction > 4 Log, in clean and dirty condition**
Method Used	**EN 14563 Quantitative carrier test for the evaluation of mycobactericidal or tubercolicidal activity of chemical disinfectants used for instruments in the medical area. (IBL = 10^9 R ≥ 4 log, in clean and dirty condition)**
Strains Employed	*Mycobacterium smegmatis CIP 7326* *Mycobacterium terrae ATCC 15755* *Mycobacterium avium ATCC 15769*
Result	**Contact Time: 5'- Reduction > 4 Log, in clean and dirty condition**

Virucidal Activity UNI EN 14885: 2019

Method Used	**EPA USA DIS/TSS 07**
Strain Employed	*HIV 1 Virus*
Result	**Reduction ≥ 97.5% (test performed by the Virology Section of the Department of Experimental Medicine, *La Sapienza* University of Rome-Italy)**

Method Used	**EPA USA DIS/TSS 07 Test performed by the Virology Section of the Department of Experimental Medicine, *La Sapienza* University of Rome-Italy)**
Strains Employed	**EMC (Encefalomiocardite) Picornaviridae**
Result	**Reduction > 70%**

Fungicidal Activity UNI EN 14885: 2019

Method Used	**EN 1650 Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants.** **(IMC = 10^7 R ≥ 4 log, in clean and dirty condition)**
Strains Employed	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
Result	**Contact Time: 5'- Reduction > 4 Log, in clean and dirty condition**
Method Used	**EN 13624 Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants.** **(IMC = 10^7 R ≥ 4 log, in clean and dirty condition)**
Strains Employed	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
Result	**Contact Time: 5'- Reduction > 4 Log, in clean and dirty condition**
Method Used	**EN 14562 Quantitative carrier test for the evaluation of fungicidal and yeasticidal activity for instruments used in the medical area.** **(IMC = 10^8 R ≥ 4 log, in clean and dirty condition)**
Strains Employed	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
Result	**Contact Time: 5'- Reduction > 4 Log, in clean and dirty condition**

Bactericidal Activity UNI EN 14885: 2019

Method Employed	**EN 1276 Quantitative suspension test for the evaluation of bactericidal activity in the food, industrial, domestic and institutional area.** **(IBL = 10^8 R ≥ 5 log, in clean and dirty condition)**
Strains Employed	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *E. Coli ATCC 10536* *Enterococcus Hirae ATCC 10541*
Result	**Contact Time: 5' -Reduction > 5 Log, in clean and dirty condition**
Method Used	**EN 13727 Quantitative suspension test for the evaluation of bactericidal activity in the medical area.** **(IBL = 10^8 R ≥ 5 log, in clean and dirty condition)**
Strains Employed	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Enterococcus Hirae ATCC 10541*
Result	**Contact Time: 5'- Reduction > 5 Log, in clean and dirty condition**
Method Used	**EN 14561 Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area.** **(IBL = 10^9 R ≥ 5 log, in clean and dirty condition)**
Strains Employed	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Enterococcus Hirae ATCC 10541*
Result	**Contact Time: 5'- Reduction > 5 Log, in clean and dirty condition**

KEY:

IBL = Initial Bacterial Load
R = Reduction of Bacterial Load Required
CFU = Colony Forming Units
IMC = Initial microbial charge/titre

5. Uses

The product is used in a 1:400 dilution.
Immerse instruments for 5 minutes, then rinse and dry before the next stage of sterilization. The product can be used in ultrasound tanks, in sterilizing and disinfecting machines and wherever decontamination is required.

6. Toxicological Information

Pharmacological data for surfactants are given below:

DL_{50} oral on rat	300 – 2000 mg/kg
DL_{50} skin on rat	>1000 mg/kg

General effects: nausea and vomiting if swallowed
No sign of skin intolerability has been found for Adazone.

7. Warnings

Warning: Hazard
(H) Hazard statements:
(H226): Flammable liquid and vapour. **(H302):** Harmful if swallowed. **(H318):** Causes serious eye demage. **(H315):** Causes skin irritation. **(H412)**: Harmful to aquatic organism with long lasting effects. **(EUH208)** Contains: SUBTILISIN. May cause an allergenic response.
(P) Precautionary statements:
(P210) Keep away from heat/sparks/open flames/ and other ignition sources-No smoking. **(P280)** Wear protective gloves/protective clothing/eye protection/face protection. **(P305+P351+P338)** IF IN CONTACT WITH EYES: Rinse thoroughly with water for several minutes. Remove contact lenses if easy to do. Continue rinsing.
(P310): Immediately call a POISON CONTROL CENTER. **(P501):** Dispose of contents/container in accordance with local/regional/national/international regulation.
Contains: CHLORIDE DIDECYLDIMETHYLAMMONIUM POLY (OXY-1,2-ethanediyl), ALPHA-OMEGA-Tridecyl-HIDROXY-BRANCHED
Warnings: The product should be handled by trained personnel according to safety regulations.
Do not swallow. Keep away from children's reach. Store in a dry place at room temperature away from heat sources.
The expiry date refers to a correct stored unopened product. Do not use the product after its expiry date. Do not disperse the container in the environment after its use (in the label it is shown as symbol). The product in its working concentration does not show adverse effects.

8. Physical and Chemical Properties

Appearance	Clear liquid
Colour	Blue
Specific Weight	1.0 – 0.2
pH	7.5 +/- 1.0

9. Quality Control

The company operates according to the Certified UNI EN ISO 9001 – UNI CEI EN ISO 13485 Quality System.

10. Validity period

36 months for correctly stored products with intact packaging.

11. Preservation modalities

Keep in a dry place at room temperature, away from heat sources.

12. Capacity and material of containers

Bottles are made of white pigmented high density polyethylene (HDPE); Lids are polyethylene (PE) and contain seals and rings.

13. Manufacturer's Name and Address

CANTEL MEDICAL (ITALY) S.r.l.
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14. Date of Issue:

	STATUS AND REASONS FOR REVISIONS	
Ed. 1	Rev. 0 Date 15.07.2019	Change of Notified Body (CE0051)
	Rev. 1 Date 12.12.2019	Update of the UNI EN 14885: 2019 standard
	Rev. 2 Date 23.01.2020	Implementation of the disinfectant claim following the Non Conformity received regarding the classification.