Cantel Medical (Italy) S.R.L.
Via Laurentina 169
00071 POMEZIA (RM)

TECHNICAL DATA SHEET

NEO PROTEOZIM PLUS 500

MEDICAL DEVICE - *Class IIb*

IDENTIFICATION CODE NPP/CE/14

1. Name of Device

NEO PROTEOZIM PLUS 500

2. Qualitative and quantitative composition

- **Total Enzymes** **0.5 %**
- **Non-ionic surfactants** **< 40%**
- **Cationic surfactant** **< 20 %**
- **Coformulants and purified water as needed**

3. Product Performance

Effective multi-enzyme detergent, decontaminant, and disinfectant for invasive and non-invasive ***medical devices*** that require thorough cleaning in channels and indentations. It is formulated with high-purity enzymes that ensure the immediate dissolution of fats, starches, proteins and other materials from difficult to access areas of the instruments.

The disinfectant activity due to the synergy between the various components has been verified for its bactericidal, virucidal, and fungicidal activity according to the standard **CEN/TC 216**.

It is used primarily in medical and dental clinics, hospitals nursing homes and wherever disinfection of ***invasive and non-invasive medical devices.***

4. Microbiological properties and activity in compliance with UNI EN 14885:2019 "Application of European Standards for chemical disinfectants and antiseptics"

Methods and results obtained

Mycobactericidal activity according to UNI EN 14885:2019	
Method followed	**EN 14348 quantitative test of mycobactericidal activity in suspension in medical area (CBI = 10^9 R ≥ 4 log, in Clean and Dirty condition)**
Strain used	*Mycobacterium Smegmatis* CIP 7326
Result	Contact time: 10' Reduction > 4 log, in Clean and Dirty condition
Method followed	**EN 14563 quantitative test of mycobactericidal activity on carrier in medical area (CBI = 10^9 R ≥ 4 log, in Clean and Dirty condition)**
Strain used	*Mycobacterium Smegmatis* CIP 7326
Result	Contact time: 10' Reduction > 4 log, in Clean and Dirty condition
Bactericidal activity according to UNI EN 14885:2019	
Method followed	**EN 1276 quantitative test in suspension for the determination of the bactericidal activity in the presence of interfering substances. (CBI = 10^8 R ≥ 5 log, in Clean and Dirty condition)**
Strains used	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Escherichia coli* ATCC 10536 *Enterococcus hirae* ATCC 10541
Result	For contact times of 10 minutes, bacterial load reduction > 5 log for all strains considered, in clean and dirty conditions.
Method followed	**EN 13727 quantitative test in suspension for the**

	determination of the bactericidal activity in medical areas **(CBI = 10^8 R ≥ 5 log, in Clean and Dirty condition)**
Strains used	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Enterococcus hirae* ATCC 10541
Result	For contact times of 10 minutes, bacterial load reduction > 5 log for all strains considered, in clean and dirty conditions.
Method followed	**EN 14561 quantitative test on carrier for the determination of the bactericidal activity in medical areas** **(CBI = 10^9 R ≥ 5 log, in Clean and Dirty condition)**
Strains used	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Enterococcus hirae* ATCC 10541
Result	For contact times of 10 minutes, bacterial load reduction > 5 log for all strains considered, in clean and dirty conditions.
Bactericidal-fungicidal activity according to UNI EN 14885:2019	
Method followed	**- EN 13697- Quantitative suspension Test on non-porous surface**
Strains used	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Candida albicans* ATCC 10231
Result	For contact times of 10 minutes, reduction of bacterial load > 4 log for all strains considered, in clean and dirty condition.
Fungicidal activity according to UNI EN 14885:2019	
Method followed	**EN 1650 quantitative test in suspension for the determination of the fungicidal activity in the presence of interfering substances.** **(CMI = 10^7 R ≥ 4 log, in Clean and Dirty condition)**
Strains used:	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
Result:	For contact times of 10 minutes, bacterial load reduction > 4 log for all strains considered, in clean and dirty conditions.
Method followed	**EN 13624 quantitative test in suspension for the determination of the fungicidal activity in the presence of interfering substances.** **(CMI = 10^7 R ≥ 4 log, in Clean and Dirty condition)**
Strains used:	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
Result:	For contact times of 10 minutes, bacterial load reduction > 4 log for all strains considered, in clean and dirty conditions.
Method followed	**EN 14562 quantitative test in suspension for the determination of the fungicidal activity in the presence of interfering substances.** **(CMI = 10^7 R ≥ 4 log, in Clean and Dirty condition)**
Strains used	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
Result	For contact times of 10 minutes, bacterial load reduction > 5 log for all strains considered, in clean and dirty conditions.

Virucidal activity according to UNI EN 14885:2019	
Method followed	**–EN 13610 - Quantitative Suspension Test**
Strains used	*Lactococcus lactis subsp lactis* F7/2 *Bacteriophage* P001 or P008
Result	for contact times of 10 minutes, reduction of bacteriophage infectivity > 4 log.

5. Method of Use

Use diluted 1:500 for the decontamination of dirty instruments immediately following use (Italian Ministerial Decree 28-9-90), for cleaning and disinfecting ***invasive and non-invasive medical devices***, in particular endoscope instruments.
Immerse the instruments for 10 minutes, then rinse and dry.
Used in ultrasonic tanks, the detergent and decontamination time can be reduced to 5 minutes. For the preparation of the solution 1:500, pour 10 ml of product and add water to reach a final volume of 5 litres.

6. Toxicological information

The pharmacological data relevant to the surfactants are the following:
for cationic surfactants:
- DL_{50} oral on rat: from 300 to 2000 mg/kg
- DL_{50} skin on rat: > 1000 mg/kg

General effects: nausea and vomiting, if swallowed.
For non-ionic surfactants:
- DL_{50} oral on rat: > 2000 mg/kg
- DL_{50} skin on rat: > 3000 mg/kg

General effects: nausea and vomiting, if swallowed.

7. Warnings

Warnings and precautions

Warnings: Danger
(H) Hazard statements:

H225	Highly flammable liquid and vapour.
H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H412	Harmful to aquatic organisms with long-lasting effects.

(P) Precautionary Statements:

P210	Keep away from heat sources, hot surfaces, sparks, open flames and other ignition sources. Do not smoke.

P273	Avoid release to the environment.
P280	Wear protective gloves / protective clothing and eye / face protection.
P303+P361+P353	IN THE EVENT OF CONTACT WITH SKIN (or with hair): Remove all contaminated clothing immediately. Rinse the skin / take a shower.
P305+P351+P338	IN CASE OF CONTACT WITH EYES: Rinse thoroughly with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
P390	Absorb leaks to avoid material damages.
Contains:	Quaternary ammonium compounds, benzyl-C12-16 alkyldimethyl, chlorides POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HYDROXY-, BRANCHED/ Mixture of: 5-chloro-2-methyl-2H-isothiazol-3-one [EC no. 247-500-7], 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1) SUBTILISIN

Keep out of the reach of children. Keep at ambient temperature, keep away from heat sources. The expiration date refers to the product in an unopened packaged that has been stored correctly. Do not use after the expiration date. When diluted for use, the product has no risk indications. The product must be handled only by expert personnel under suitable safety standards.

8. Physical and Chemical Characteristics

APPEARANCE	CLEAR LIQUID
COLOUR	LIGHT BLUE
SPECIFIC GRAVITY	1.0 ± 0.2
pH	6.0 - 8.5
CATIONIC SURFACTANT	14.5 ± 0.25 %

9. Quality Control

The company has a total quality system certified UNI EN ISO 9001 - UNI CEI EN ISO 13485 and as GLP testing centre. In the production process and control, it applies the same standards (GMP - Good Manufacturing Practices) required for the production of pharmaceuticals.

10. Period of Validity

36 months for the product in an unopened packaged that has been stored correctly.

11. Method of Storage

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

12. Type and capacity of containers

The bottles and containers are made from HDPE; the caps are PE and equipped with ring sealed caps.

PACKAGING	
PRIMARY	***SECONDARY***
500 ml bottle	**24 bottles**
1000 ml bottle	**12 bottles**
2000 ml bottle	**6 bottles**
5000 ml container	**4 containers**

13. Manufacturer's Name and Address

Cantel Medical (Italy) S.r.l.
Via Laurentina, no. 169 Pomezia (Rome) Italy
Tel. + 39 06/9145399
Processing plant

14. Date of completion:

STATUS AND REASON FOR THE REVISIONS		
Ed. 1	Rev.0 dated 21.06.2019	Notified Body's change (CE 0051)
	Rev.1 dated 12.12.2019	Update of the UNI EN 14885: 2019 standard
	Rev.2 dated 02.04.2021	Update of Physical and Chemical Characteristics table