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

TECHNICAL DATA SHEET

BACTRYL® SPRAY

MEDICAL DEVICE *class IIb*

CODE CODE. ISAS/CE/45

1. Device Name

Bactryl® Spray

2. Qualitative and quantitative composition

100 ml contain

Isazone®	g < 0.05
Benzalkonium chloride 50%	g < 1
Chlorhexidine digluconate 20%	g < 1
Co-formulants and purified water	q.s. to ml 100.00

3. Product presentation

Bactryl® Spray is a cleanser, disinfectant for cleaning and disinfection active on common surfaces and on invasive and non-invasive Medical Devices. It comes in the form of clear light blue solution.

The presence of Benzalkonium chloride gives a residual bacteriostatic effect.
It is packed in white pigmented HDPE bottles, labelled upon packaging.

4. Activity and microbiological properties

Bactryl® Spray is a detergent, disinfecting product with a broad spectrum of activity against gram +, gram- bacteria, fungi, yeast, mycobacteria and enveloped viruses. The association of Isazone® with Benzalkonium chloride and Chlorhexidine digluconate speeds up its action.
It is therefore suitable for the aseptic disinfection and preservation of Medical Devices.

4.1. Activity and microbiological properties, according to UNI EN 14885:2019: "Application of European standards for chemical disinfectants and antiseptics"

Bactericidal Activity	
Method used	**EN 13727: quantitative suspension test for the evaluation of bactericidal activity in medical area (Clean and Dirty condition) TEST BY HYGCEN** **(CBI = 10^8 ufc/ml R ≥ 5 log)**
Strains used	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P; MRSA *Enterococcus hirae* ATCC 10541 *Proteus mirabilis* ATCC 14153
Result	**contact time: 1' – reduction > 5 log on bacteria, in both Clean and Dirty condition**
Method used	**EN 13727: quantitative suspension test for the evaluation of bactericidal activity in medical area (Clean and Dirty condition)** **(CBI = 10^8 ufc/ml R ≥ 5 log)**
Strains used	*Salmonella enterica typhimurium ATCC 13311* *Salmonella choleraseus ATCC 10708*
Result	**contact time: 10' - reduction > 5 log on *Salmonella enterica typhimurium ATCC 13311, Salmonella choleraseus* ATCC 10708, in both Clean and Dirty condition**

Fungicidal Activity	
Method used	**EN 13624: quantitative suspension test for the evaluation of fungicidal activity in medical area (Clean and Dirty condition) TEST BY HYGCEN** **(CMI = 10^7 ufc/ml R ≥ 4 log)**
Strains used	*Candida albicans* ATCC 10231
Result	**contact time: 1' – reduction > 4 log on *Candida albicans* ATCC 10231, in both Clean and Dirty condition**
Method used	**EN 13624: quantitative suspension test for the evaluation of fungicidal activity in medical area (Clean and Dirty condition)** **(CMI = 10^7 ufc/ml R ≥ 4 log)**
Strains used	*Aspergillus niger* ATCC 16404 *Trichophyton mentagrophytes* ATCC 9533
Result	**contact time: 5' – reduction > 4 log on *A. brasiliensis* (ex niger) ATCC 16404, in both Clean and Dirty condition**
	contact time: 10' – reduction > 4 log on *Trichophyton mentagrophytes* ATCC 9533, in both Clean and Dirty condition
Bactericidal – Fungicidal activity on surfaces	
Method used	**EN 13697: quantitative suspension test for the evaluation of bactericidal - fungicidal activity in the presence of interfering substances (Clean and Dirty condition) TEST BY HYGCEN** **(CMI = 10^7 ufc/ml R ≥ 4 log for bacteria)** **(CMI = 10^7 ufc/ml R ≥ 3 log for fungi)**
Strains used	*Staphylococcus aureus* ATCC 6538P *Enterococcus hirae* ATCC 10541 *Escherichia coli* ATCC 10536 *Pseudomonas aeruginosa* ATCC 15442 *Candida albicans* ATCC 10231
Result	**contact time: 1' – reduction > 4 log for bacteria** **- reduction > 3 log for fungi** **in both Clean and Dirty condition**
Method used	**EN 13697: quantitative suspension test for the evaluation of bactericidal - fungicidal activity in the presence of interfering substances (Clean and Dirty condition)** **(CMI = 10^7 ufc/ml R ≥ 4 log for bacteria)** **(CMI = 10^7 ufc/ml R ≥ 3 log for fungi)**
Strains used	*Salmonella enterica typhimurium ATCC 13311* *Salmonella choleraseus ATCC 10708* *Aspergillus niger* ATCC 16404 *Trichophyton mentagrophytes* ATCC 9533
Result	**contact time: 10' – reduction > 4 log for bacteria** **- reduction > 3 log for fungi** **in both Clean and Dirty condition**
Method used	**EN 16615 Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces**

	with mechanical action employing wipes in the medical area (4- field test) - Test method and requirements (phase 2, step 2) **CMI = 10^9 ufc/ml R ≥ 4 log for Bacteria cells, CMI= 10^8 for *C. albicans* ATCC 10231))**
Strains used	*Pseudomonas aeruginosa ATCC 15442* *Staphylococcus aureus ATCC 6538* *Enterocccus hirae ATCC 10541* *Candida albicans ATCC 10231*
Result	**contact time: 30'' – reduction > 5 log for bacteria** **- reduction > 4 log for fungi** **in both Clean and Dirty condition**
Virucidal Activity	
Method used	**EN 14476 Quantitative suspension test for the evaluation of virucidal activity (Dirty condition) – Test performed at La Sapienza, University of Rome – Virology Dept.** **R ≥ 4 log**
Strains used	HIV USUV surrogate for HCV VSV surrogate for HBV
Result	**contact time: 1'- reduction of viral replication R≥ 4,0 log**
Method used	**EN 14476 Virucidal activity against enveloped virus - Quantitative test modified for HBV and HCV (non surrogate wild strains) for the evaluation of virucidal activity by molecular assay-real time PCR method – Test performed at La Sapienza, University of Rome – Virology Dept.** **(Reduction levels %)**
Strains used	*HBV, HCV*
Result	**HBV: 78% - 1' contact time** **HCV: 87% - 1' contact time**
Method used	**Quantitative suspension test according to the Guideline of the Robert-Koch-Institute RKI (German Federal Health Authority) and the Deutsche Vereinigung zur Bekämpfung der Viruserkrankungen DVV (German Registered Association for Combating Viral Diseases)**
Strains used	*BVDV-Vaccinia Virus Strain Ankara HIV, HBV,HCV e influenza viruses*
Result	**Effective against enveloped viruses:** **undiluted / 1 min**
Mycobactericidal Activity	
Method used	**EN 14348 quantitative suspension test for the evaluation of mycobactericidal activity against mycobacteria (Clean and Dirty condition)** **(CMI = 10^8 ufc/ml R ≥ 4 log)**
Strains used	*Mycobacterium smegmatis* CIP 7326 *Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755

Result	**contact time: 2' – reduction > 4 log on *M. smegmatis* CIP 7326, in both Clean and Dirty condition**
	contact time: 5 ' – reduction > 4 log on *Mycobacterium avium ATCC 15769* and *Mycobacterium terrae ATCC 15755*, in both Clean and Dirty condition

LEGEND:

IBL/IML	**= Initial bacterial load/initial microbial load**
R	**= Expected reduction of bacterial/microbial load**
cfu	**= colony-forming units**
pfu	**= plaque-forming units**

5. Directions for use

Bactryl® Spray is a cleaning and disinfectant solution for surfaces and on Medical Devices, active in 1 minute (EN 14885 – disinfection for surfaces) and in 30 seconds if rubbed on with a towel/cloth (EN 16615).
Bactryl Spray® should be used as is, without dilution.

Directions for use: use it as is, without dilution. After putting on the Personal Protective Equipment (PPE), apply the detergent/disinfectant with a spray bottle to common and Medical Device surfaces and wait the expected contact time.

Rinse off the Medical Devices before use if expected.
The product should be used by qualified staff in compliance with effective safety regulations.
Storage: leave the medical devices immersed in the solution after washing and drying them. Pick the disinfected devices from the tray following an aseptic procedure and rinse them with sterile water.
Compatibility: the solution is highly compatible with the materials constituent the medical devices and the main surfaces in hospitals and dental practice (including handles, lamps, chairs).

6. Toxicological Information

Acute toxicity	
for benzalkonium chloride	DL_{50} oral rat: 400 mg/kg
- General effects	nausea and vomiting, if ingested in large quantities;

7. Warning

For use in hospitals, and medical and dental practice. The product should be used by qualified staff in compliance with effective safety regulations.

Warning: Hazard.

(H) Hazard statements:

H225 Liquid and vapors highly flammable.
H319 Causes severe eye irritation.
H412 Harmful to aquatic organisms with long-term effects.

(P) Prevention precautionary statements:

P210 Keep away from heat sources, hot surfaces, sparks, open flames or other ignition sources. Do not smoke.
P280 Wear protective gloves and eye protection/face protection.
P305+P351+P338 IF IN EYES: rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
P337+P313 If the eye irritation persists, seek medical advice.
P273 Do not dispose of it in the environment.

Keep out of reach of children.
Keep in a dry place at room temperature, away from heat sources. The expiry date refers to the product stored properly, in original package. Do not use after expiration date.

8. Physical and chemical properties

appearance	clear liquid
odour	citrus light
colour	light blue
specific weight	0.95-1.05 g/cm^3
pH	5.5-7.5

9. Quality checks

The company operates under a fully certified Quality Management System as per UNI EN ISO 9001 - EN 13485.

10. Shelf-life

24 months for the product properly stored in original packaging.

11. Storage conditions

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

12. Type and capacity of containers

PE bottles closed with ring-nut caps.
The product is packaged in bottles of 1000 ml.
The 1000 ml bottles are further packed in a cardboard box containing 4 bottles, with 2 nozzles (sprays) inside.

13. Name and address of the holder of the certification

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Independent production laboratory

14. Compilation date:

Ed.	Rev.	Date	STATUS AND REASON OF REVISIONS
1	0	25.06.2019	Change of Notified Body (CE0051)
	1	28.11.2019	Revision of paragraphs 3, 4 and 5 to specify the action on surfaces. Revision of paragraph 4.1 for updating the applied standards and for updating the edition of the UNI EN 14885: 2019 standard.