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

TECHNICAL DATA SHEET

BACTRYL® WIPES

MEDICAL DEVICE *class IIb*

CODE CODE. ISAS/CE/45

1. Device Name

Bactryl® Wipes

2. Qualitative and quantitative composition

Composition of the wetting solution

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

Composition of wipes

TNT (non-woven fabric).

3. Product presentation

Bactryl® Wipes is a detergent, disinfecting product for cleaning and disinfection of surfaces and on invasive and non-invasive Medical Devices. It comes in the form of wipes soaked in a clear light blue solution.

The presence of Benzalkonium chloride gives a residual bacteriostatic effect.

The product is packed in labelled jars, labelled, containing 110 disposable wipes.

4. Activity and microbiological properties

Bactryl® Wipes 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.

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® Wipes is a ready-to-use cleaning and disinfecting solution with bactericidal, virucidal, fungicidal, yeasticidal and mycobactericidal action on Medical Devices, effective in 30 seconds (EN 16615) and 1 minute (EN 14885 disinfection for surfaces).

Directions for use: After putting on the Personal Protective Equipment (PPE), wipe surfaces and medical devices evenly with the wipe and wait for the expected contact time.
Rinse off the medical devices before use if expected.

Instructions for use:
1) Remove the lid and the protection plug.
2) Pull out the loose section of the wipe from the centre of the roll and insert it into the eyelet in the middle of the lid.
3) Fix the lid and pull out the wipe until you can see the pre-cut section; firmly tear off the wipe, locking the next wipe with the plug in the middle of the lid.

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

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.

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

Characteristics of the disinfecting solution:

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

Characteristics of the wipe:

appearance	nonwoven, white, translucent fabric
dimensions	cm 14 x 25 ; (110 wipes)

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

The jars are made of high density polyethylene (HDPE), white pigmented; the protective caps and the lids are made of polyethylene (PE).
The jars are further packed in a cardboard box containing 6 jars.

13. Name and address of the holder of the certification

Cantel Medical (Italy) S.r.l.
Via Laurentina, n. 169 Pomezia (Roma)
Ph. +39.06/9145399
Independent production laboratory

14. Compilation date:

Ed.	Rev.	Date	STATUS AND REASON OF REVISIONS
1	0	25.06.2019	Change of Notifed Body (CE 0051)

	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.