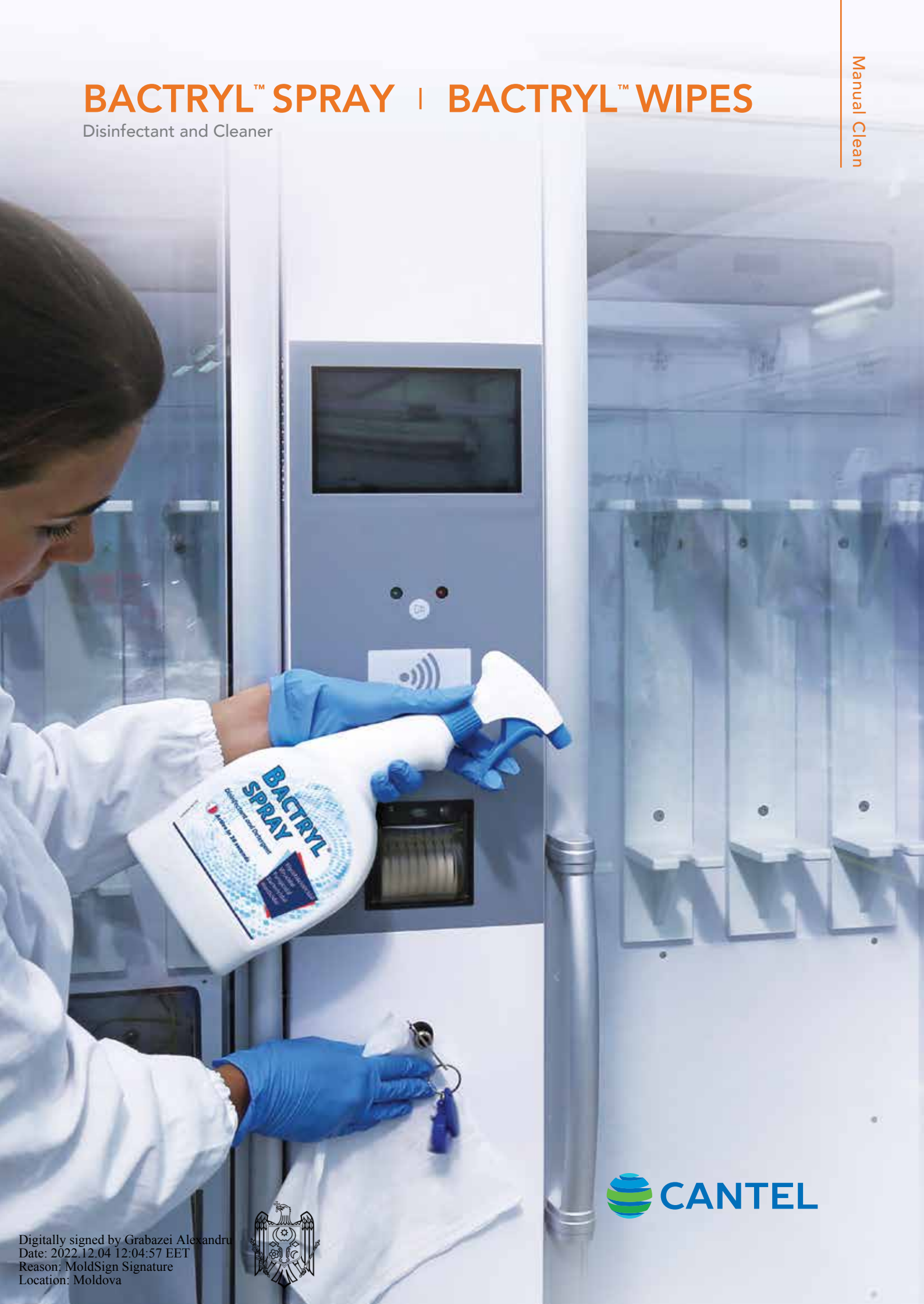
BACTRYL™ SPRAY | BACTRYL™ WIPES

Disinfectant and Cleaner

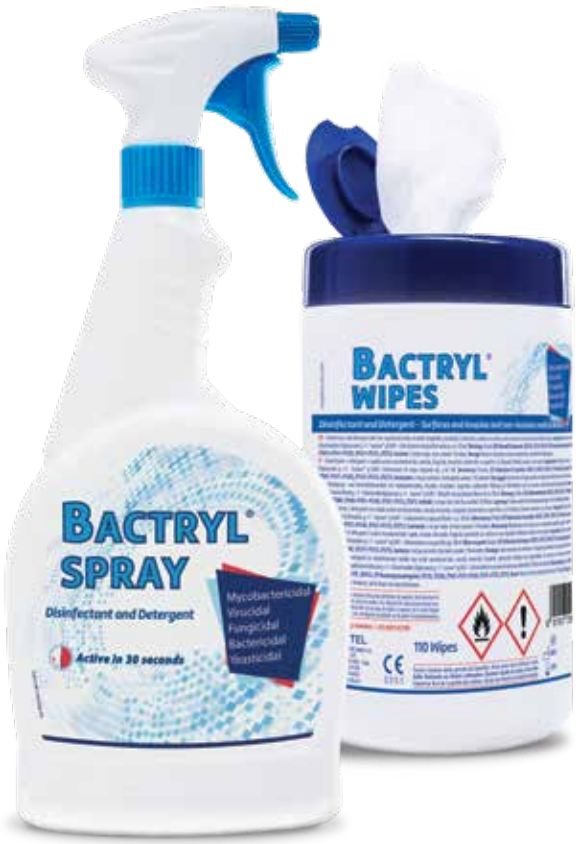
Manual Clean



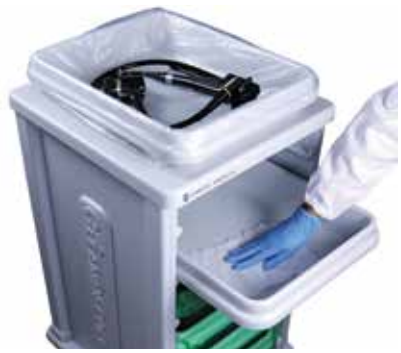
CANTEL

BACTRYL™ DISINFECTANT

Powerful disinfectant and surface cleaner, available in both spray and wipes



Ready-to-use cleaning and disinfecting agent with bactericidal, virucidal, fungicidal, yeasticidal and mycobactericidal properties on surfaces and on invasive and non-invasive medical devices. It is a class IIb Medical Device

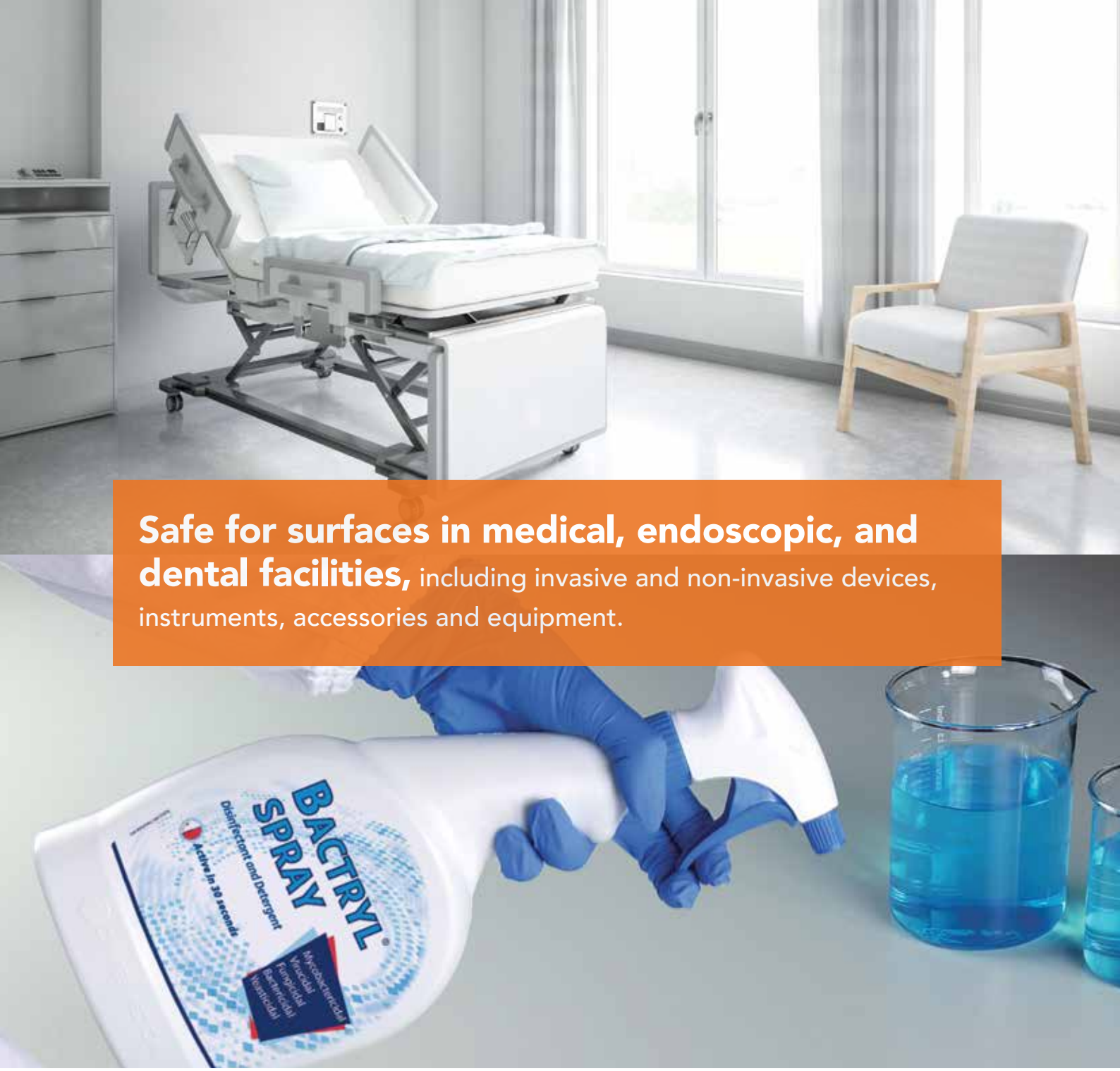


Effective cleaning and disinfection

- Tested by two accredited laboratories and approved by independent experts[1,2]
- Double action in one product, cleaning and disinfection, thanks to the combination of quaternary ammonium compounds and chlorhexidine
- Registered on the VAH-List of Disinfectants (The Association for Applied Hygiene, Germany)
- Have demonstrated complete inactivation of enveloped viruses such as MVA, BVDV, HIV, HBV, Coronavirus, and Influenza

Tested compatibility

- Compatible with a wide range of materials, including HDPE, Teflon, PVC, PET, silicone, neoprene rubber, and metals such as aluminum and stainless steel
- Can be used with invasive and non-invasive devices
- Gentle and safe for surfaces, Neutral pH



Safe for surfaces in medical, endoscopic, and dental facilities, including invasive and non-invasive devices, instruments, accessories and equipment.

Safe and easy to use

- Ready to use—just spray and wait, or spray and wipe for faster action
- Safe for operators, contains no carcinogenic, mutagenic, or toxic ingredients
- No bleach, no aldehydes, no phenols
- Broad application throughout your medical or dental site

Rapid and lasting action

- Disinfectant in 1 minute on bacteria, yeast and enveloped viruses (in compliance with EN 14885)
- Disinfectant in 30 seconds on bacteria and yeast if rubbed on with a towel/cloth (EN 16615)
- Fungicidal and Mycobactericidal activity between 2-10 minutes according to the stains

BACTRYL™ Disinfectant meets the relevant requirements of European Directives for a wide spectrum of action.

In compliance with EN 14885 and EN 16615 (surface disinfectant)

DISINFECTANT ACTIVITY

ACTIVITY	STANDARD
Bactericidal*	EN 13727, EN 13697 *Pseudomonas aeruginosa, Staphylococcus aureus, E. coli, Enterococcus hirae, Salmonella enterica typhimurium, Salmonella choleraseus, Proteus mirabilis.*
Fungicidal/Yeasticidal*	EN 13624, EN 13697 *Candida albicans, Aspergillus niger, Trichophyton mentagrophytes*
Bactericidal/Yeasticidal	EN 16615 *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Enterocccus hirae* ATCC 10541, *Candida albicans* ATCC 10231
Mycobactericidal/ Tubercolicidal	EN 14348 *M. smagmatis, M. avium, M. terrae*
Virucidal**	EN14476 (HIV, HBV, HCV) DVV/RKI (enveloped viruses)** BVDV, Vaccinia Virus Strain Ankara HIV, HBV, HCV e influenza viruses.

* Tested according to requirements and methods for VAH Certification of Chemical Disinfection procedures. VAH Listed.

** Validated in external lab in 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).

ORDERING INFORMATION

PART NUMBER	DESCRIPTION	UNITS PER BOX
500046	Bactryl Spray, Bottle of 1000 ml	4 bottles
500047	Bactryl Wipes, Tube with 110 wipes	6 tubes

Bench tested and confirmed with two independent labs.

Tests performed in clean and dirty conditions.

Recommended for use with Cantel capital equipment.

Use with confidence on Cantel equipment such as: CLEANASCOPE™ System Carts and Trays, SURESTORE™ Endoscope Storage & Transportation, ENDODRY™ Drying and Storage System, ISA™ Automated Endoscope Reprocessor, ADVANTAGE PLUS™ Automated Endoscope Reprocessor, ADVANTAGE PLUS™ Pass-Thru Automated Endoscope Reprocessor, RAPIDAER™ Endoscope Reprocessor along with a wide range of other health care cleaning and disinfection applications.

THE COMPLETE CIRCLE OF PROTECTION

As the global vanguard in infection prevention, **only Cantel delivers the Complete Circle of Protection**, a full-value, proactive partnership dedicated to helping you remove risk, streamline operational efficiencies and optimize your success.

References
1. H.P. Werner. HygCen Germany. (2018, February). Test report SN 24115 of 2017-02-27.
2. F.A. Pitten. HygCen Germany. (2018, June). Test report PL 18-46 180615

www.cantelmedical.eu

Global Headquarters | **p:** +1.973.890.7220

TO PLACE AN ORDER
Medivators B.V. | **p:** +31455471471 (customer service) **e:** csdistributors@medivators.com
Cantel (Germany) GmbH | **p:** +4921190980750 **e:** CSDE@cantelmedical.de
Cantel Medical (Italy) srl | **p:** +39069145399 **e:** info@cantelmedical.it

CANTEL

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

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 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.

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.

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

CANTEL MEDICAL (ITALY) SRL

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

has implemented and maintains a

Quality Management System

for the following scope:

Design, development, manufacturing of disinfectants, sterilizers and detergents for medical devices. Design, development, production, sales and technical service of device for washing, disinfection and sterilization of medical devices. Design, development, production management of conservation and transport systems for endoscopes

Further clarifications regarding the applicability of UNI CEI EN ISO 13485:2016 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

UNI CEI EN ISO 13485:2016

Issued on: **2021 - 01 - 21**
Expires on: ***2024 - 07 - 05***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 126041

Alex Stoichitoiu
President of IQNET

Ing. Mario Romersi
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

www.imq.it

CISQ is a member of

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. 1250.2019

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CANTEL MEDICAL (ITALY) SRL

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, sviluppo, produzione di disinfettanti, sterilizzatrici e detergenti per dispositivi medici. Progettazione, sviluppo, produzione, commercializzazione e assistenza tecnica di dispositivi per il lavaggio, la disinfezione e la sterilizzazione di dispositivi medici. Progettazione, sviluppo, gestione della produzione di sistemi di conservazione e trasporto di endoscopi
Design, development, manufacturing of disinfectants, sterilizers and detergents for medical devices. Design, development, production, sales and technical service of device for washing, disinfection and sterilization of medical devices. Design, development, production management of conservation and transport systems for endoscopes

Ulteriori informazioni riguardanti l'applicabilità dei requisiti UNI CEI EN ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of UNI CEI EN ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1997-07-25	2021-01-21	2024-07-05

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

La data di prima certificazione è riferita al rilascio da parte di altro Organismo
First certification date is related to issue date of another Certification Body

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

IMQ

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

CERTIFICATO CE

Certificato n. 1812/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

CANTEL MEDICAL (ITALY) SRL

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

mantiene nello stabilimento di:

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Lava disinfettatrice-sterilizzatrice chimica a freddo per endoscopi

Sterilizzanti chimici a freddo per dispositivi medici

Disinfettanti per dispositivi medici

Detergente plurienzimatico decontaminante disinfettante per dispositivi medici

Disinfettanti, decontaminanti e detergenti per dispositivi medici

Disinfettanti e detergenti per dispositivi medici

Disinfettanti e decontaminanti per dispositivi medici

Sistemi di conservazione e trasporto di endoscopi

Lava disinfettatrice per endoscopi

serie e modelli indicati in Allegato

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

DM15A0449933-01; DM15E0572628-01; DM16A0607476-01; DM16-0000589; DM16-0002190-01; DM19-0043082-01; DM19-0043104-01; DM20-0050214-01; DM20-0048482-01; DM20-0051086-01; DM20-0047938-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

IMQ

CERTIFICATO CE

Certificato n. 1812/MDD

Allegato

Lava disinfettatrice-sterilizzatrice chimica a freddo per endoscopi
Mod. MEDIVATORS ISA
Marca Cantel Medical (Italy) S.r.l.

Sterilizzanti chimici a freddo per dispositivi medici
Modd. ADASPOR PRONTO; ADASPOR CONCENTRATO, ADASPOR M CONCENTRATO; ADASPOR MONODIE; ADASPOR PENTADIE; ADASPOR SINGLE SHOT; PROLYSTICA AUTO PAA; ISASPOR SINGLE SHOT; ADASPOR PLUS SINGLE SHOT, ADASPOR PLUS PRONTO (READY TO USE); ADASPOR PLUS CONCENTRATO; ADASPOR PLUS MONODIE; ADASPOR PLUS PENTADIE, ADASPOR PLUS M CONCENTRATO.
Marca CANTEL

Disinfettanti per dispositivi medici
Modd. BLUESTERIL ALCOLICO; BLUESTERIL FERRI; BLUESTERIL SPRAY.
Marca CANTEL

Detergente plurienzimatico decontaminante disinfettante per dispositivi medici
Modd. NEO PROTEOZIM PLUS 500; PROTEOZIM PLUS 400.
Marca CANTEL

Disinfettanti, decontaminanti e detergenti per dispositivi medici
Mod. ISACLEAN, PROTEODONT.
Marca CANTEL

Disinfettanti e detergenti per dispositivi medici
Modd. BACTRYL SPRAY; BACTRYL WIPES; ISACLEAN SPRAY; SPOREXIN SPRAY; SPOREXIN WIPES; SPOREXIN VACUUM.
Marca CANTEL

Disinfettanti e decontaminanti per dispositivi medici
Modd. PROTEAZONE; PROTEAZONE OD.
Marca CANTEL

Sistemi di conservazione e trasporto di endoscopi
Modd. CLEANASCOPE; CLEANASCOPE ADVANTAGE.
Marca CANTEL

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Emesso il:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

DocuSign

IMQ

CERTIFICATO CE

Certificato n. 1812/MDD

Allegato

Lava disinfettatrice per endoscopi
Modd. INNOVA E3s; INNOVA E3s CMS; INNOVA E4s CMS.
Marca CANTEL

Emesso il:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

IMQ

EC CERTIFICATE

Certificate No 1812/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

CANTEL MEDICAL (ITALY) SRL

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

manages in the factory of:

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Cold chemical washer disinfector and sterilizer for endoscopes

Cold chemical sterilant for medical devices

Disinfectants for medical devices

Multi-enzyme detergent, decontaminant disinfectant for medical devices

Disinfectants, decontaminants and detergents for medical devices

Disinfectants and detergents for medical devices

Decontaminants and disinfectants for medical devices

Storage and transport systems for endoscopes

Washer disinfector for endoscopes

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM15A0449933-01; DM15E0572628-01; DM16A0607476-01; DM16-0000589; DM16-0002190-01; DM19-0043082-01; DM19-0043104-01; DM20-0050214-01; DM20-0048482-01; DM20-0051086-01; DM20-0047938-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2015-07-20
Updated:	2020-05-08
Substitution Date:	2020-04-07
Expiry Date:	2024-05-26

DocuSign

IMQ

EC CERTIFICATE

Certificate No 1812/MDD

Annex

Cold chemical washer disinfector and sterilizer for endoscopes
Type ref. MEDIVATORS ISA
Trade mark Cantel Medical (Italy) S.r.l.

Cold chemical sterilant for medical devices
Type ref. ADASPOR PRONTO; ADASPOR CONCENTRATO, ADASPOR M CONCENTRATO; ADASPOR MONODIE; ADASPOR PENTADIE; ADASPOR SINGLE SHOT; PROLYSTICA AUTO PAA; ISASPOR SINGLE SHOT; ADASPOR PLUS SINGLE SHOT, ADASPOR PLUS PRONTO (READY TO USE); ADASPOR PLUS CONCENTRATO; ADASPOR PLUS MONODIE; ADASPOR PLUS PENTADIE, ADASPOR PLUS M CONCENTRATO.
Trade mark CANTEL

Disinfectants for medical devices
Type ref. BLUESTERIL ALCOLICO; BLUESTERIL FERRI; BLUESTERIL SPRAY.
Trade mark CANTEL

Multi-enzyme detergent, decontaminant disinfectant for medical devices
Type ref. NEO PROTEOZIM PLUS 500; PROTEOZIM PLUS 400.
Trade mark CANTEL

Disinfectants, decontaminants and detergents for medical devices
Type ref. ISACLEAN, PROTEODONT.
Trade mark CANTEL

Disinfectants and detergents for medical devices
Type ref. BACTRYL SPRAY; BACTRYL WIPES; ISACLEAN SPRAY; SPOREXIN SPRAY; SPOREXIN WIPES; SPOREXIN VACUUM.
Trade mark CANTEL

Decontaminants and disinfectants for medical devices
Type ref. PROTEAZONE; PROTEAZONE OD.
Trade mark CANTEL

Storage and transport systems for endoscopes
Type ref. CLEANASCOPE; CLEANASCOPE ADVANTAGE.
Trade mark CANTEL

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Date: 2015-07-20
Updated: 2020-05-08
Substitution Date: 2020-04-07
Expiry Date: 2024-05-26

IMQ

This is a translation of the Italian text, which prevails in case of doubts

EC CERTIFICATE

Certificate No 1812/MDD

Annex

Washer disinfector for endoscopes

Type ref. INNOVA E3s; INNOVA E3s CMS; INNOVA E4s CMS.
Trade mark CANTEL

Date:	2015-07-20
Updated:	2020-05-08
Substitution Date:	2020-04-07
Expiry Date:	2024-05-26

IMQ

This is a translation of the Italian text, which prevails in case of doubts