1. NAME OF MEDICAL DEVICE

ADASPOR™ PLUS READY TO USE

2. Qualitative and quantitative composition

Activated solution (A+B)
ISAZONE™ ($C_{20}H_{20}ON_2$) < 0.015%
Peracetic acid = 1800 – 2300 ppm
Corrosion inhibitor, bacteriostatic agent

3. Product presentation

Description of activated solution (A+B): Cold chemical sterilant solution according to UNI EN ISO 14937:2009, par. 5.3.1, ready to use with fast sporicidal, mycobactericidal, tuberculocidal, bactericidal, virucidal, fungicidal activity, for sterilization and disinfection of endoscopes and medical devices (such as surgical tools, catheters and probes, anaesthesia apparatus, inhalers, hamodialysis machines, endoscopes, urological and dental devices, etc). It can be used manually or in automated medical device reprocessors and sterilisers according to the manufacturers' instructions.
Packaging: Two bottles (36 ml of Solution A and 964 ml of Solution B) in one box.
Two bottles (200 ml of Solution A and 4800 ml of Solution B) in one box.

4. Microbiological activity and properties

Microbiological activity according to UNI EN ISO 14885:2019 "Application of European Standards for chemical disinfectants and antiseptics ".

4.1 Sterilising activity according to UNI EN ISO14937 par 5.3.1 and complying with UNI EN ISO 11138-1	
Methods employed	**UNI EN ISO 14937 par 5.3.1 and UNI EN ISO 11138-1**
Strains employed	*Bacillus subtilis* ATCC 6633 *Bacillus atropheus* ATCC 9372 *Bacillus cereus* ATCC 12826 *Clostridium sporogenes* ATCC 19404 *Geobacillus stearothermophylus* ATCC 7953 *Mycobacterium terrae* ATCC 15755 *Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404 *Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P Lipidic and non lipidic Viruses *Picornavirus (Coxsackievirus B3)* *Adenovirus Type 4*
results	**Sterilisation-contact time 10 minutes – CFU growth = 0**

4.2 Microbiological activity according to UNI EN ISO 14885:2019 " Application of European Standards for chemical disinfectants and antiseptics ".	
4.2.1 Sporicidal activity according to UNI EN ISO 14885:2019	
Methods employed	**EN 14347 – Test for sporicidal activity test** **(IBC = 10^8 R ≥ 4 log)**
Strains employed	*Bacillus subtilis* ATCC 6633 *Bacillus cereus* ATCC 12826
results	**Contact time 10 minutes – CFU growth = 0**
	Contact time 5 minutes – R ≥ 4 log
Methods employed	**EN 13704 – Test for the evaluation of sporicidal activity** **(IBC = 10^6 R ≥ 3 log, in clean condition)**
Strains employed	*Bacillus subtilis* ATCC 6633 *Bacillus cereus* ATCC 12826 *Clostridium sporogenes* ATCC 19404
results	**Contact time 10 minutes – CFU growth = 0 in clean condition**
	Contact time 5 minutes – R ≥ 3 log in clean condition

4.2.2 Mycobactericidal activity according to UNI EN ISO 14885:2019	
Methods employed	**EN 1040 - Basic mycobactericidal activity test** **(IBC = 10^8 R ≥ 5 log)**
Strains employed	*Mycobacterium terrae* ATCC 15755 *Mycobacterium avium* ATCC 15769 *Mycobacterium smegmatis* CIP 7326
results	**Contact time 10 minutes - CFU growth = 0**
	Contact time 5 minutes - R ≥ 5 log
Methods employed	**EN 14348 –Mycobactericidal activity test in the medical area.** **(IBC = 10^8 R ≥ 4 log in clean and dirty condition)**
Strains employed	*Mycobacterium terrae* ATCC 15755 *Mycobacterium avium* ATCC 15769 *Mycobacterium smegmatis* CIP 7326
results	**Contact time 10 minutes - CFU growth = 0 in clean and dirty condition**
	Contact time 5 minutes - R ≥ 4 log in clean and dirty condition
Methods employed	**EN 14563 –Mycobactericidal activity carrier test in the medical area.** **(IBC = 10^9 R ≥ 4 log in clean and dirty condition)**
Strains employed	*Mycobacterium smegmatis* CIP 7326 *Mycobacterium terrae* ATCC 15755 *Mycobacterium avium* ATCC 15769
results	**Contact time 10 minutes - CFU growth = 0 in clean and dirty condition**
	Contact time 5 minutes - R ≥ 4 log in clean and dirty condition

4.2.3 Virucidal activity according to UNI EN ISO 14885:2019	
Methods employed	**EN 14476 –Test for Virucidal activity.** **(IMC = $10^8 \div 10^9$ R ≥ 4 log in clean and dirty condition)**
Strains employed	*Murine norovirus (MNV) type S99*
results	**Contact time 10 minutes – growth inhibition in clean and dirty condition**
	Contact time 5 minutes – growth inhibition in clean and dirty condition
Methods employed	**EN 14476 –Test for Virucidal activity.** **(IMC = $10^8 \div 10^9$)**
Strains employed	*Picornavirus (Coxsackievirus B3)* *Adenovirus* type 4
results	**Contact time 10 minutes – growth inhibition**
	Contact time 5 minutes – growth inhibition

4.2.4 Fungicidal activity according to UNI EN ISO 14885:2019	
Methods employed	**EN 1275 - Basic fungicidal activity test** **(IMC = 10^7 cfu/ml R≥ 4 log)**
Strains employed	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
results	**Contact time 10 minutes – CFU growth = 0**
	Contact time 5 minutes – R≥ 4 log
Methods employed	**EN 1650 – Quantitative suspension test for the evaluation of fungicidal activity in the presence of interfering substances.** **(IMC = 107 cfu/ml R^3 4 log in dirty and clean condition)**
Strains employed	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
results	**Contact time 10 minutes – CFU growth = 0 in dirty and clean condition**
	Contact time 5 minutes – R≥ 4 log in dirty and clean condition
Methods employed	**EN 13624 – Quantitative suspension test in the medical area** **(IMC = 10^7cfu/ml R≥ 4 log in dirty and clean condition)**
Strains employed	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC16404
results	**Contact time 10 minutes – CFU growth = 0 in dirty and clean condition**
	Contact time 5 minutes – R≥ 4 log in dirty and clean condition
Methods employed	**EN 14562 – Quantitative carrier test in the medical area** **(IMC = 10^7 cfu/ml R≥ 4 log in dirty and clean condition)**
Strains employed	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
results	**Contact time 10 minutes – CFU growth = 0 in dirty and clean condition**
	Contact time 5 minutes – R≥ 4 log in dirty and clean condition

4.2.5 Bactericidal activity according to UNI EN ISO 14885:2019	
Methods employed	**EN 1040 - Basic bactericidal activity test** **(IBC = 10^8 R ≥ 5 log)**
Strains employed	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P
results	**Contact time 10 minutes – CFU growth = 0**
	Contact time 5 minutes – R ≥ 5 log
Methods employed	**EN 1276 –Bactericidal quantitative activity suspension test in the presence of interfering substances.** **(IBC = 10^8 R ≥ 5 log in dirty and clean condition)**
Strains employed	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Escherichia coli* ATCC 10536 *Enterococcus hirae* ATCC 10541
results	**Contact time 10 minutes – CFU growth = 0 in dirty and clean condition**
	Contact time 5 minutes – R ≥ 5 log in dirty and clean condition
Methods employed	**EN 13727 –Bactericidal activity suspension test in the medical area** **(IBC = 10^8 R ≥ 5 log in dirty and clean condition)**
Strains employed	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Enterococcus hirae* ATCC 10541
results	**Contact time 10 minutes – CFU growth = 0 in dirty and clean condition**
	Contact time 5 minutes – R ≥ 5 log in dirty and clean condition
Methods employed	**EN 14561 – Bactericidal activity carrier test in the medical area** **(IBC = 10^8 R ≥ 5 log in dirty and clean condition)**
Strains employed	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Enterococcus hirae* ATCC 10541
results	**Contact time 10 minutes – CFU growth = 0 in dirty and clean condition**

	Contact time 5 minutes – R ≥ 5 log in dirty and clean condition

4.2.6 Bactericidal and fungicidal activity according to UNI EN ISO 14885:2019	
Methods employed	**EN 13697 – Quantitative non porous surface test.** **(IBC =10^8 cfu/ml R ≥ 4 log- IMC = 10^7 cfu/ml R ≥ 3 log in dirty and clean condition)**
Strains employed	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538P *Escherichia coli* ATCC 10536 *Enterococcus hirae* ATCC 10541 *Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404
results	**Contact time 10 minutes - CFU growth = 0 in dirty and clean condition**
	Contact time 5 minutes - R ≥ 4 log for bacteria and R ≥ 3 log for fungi in dirty and clean condition

MRC (Minimum recommended concentration) evaluation for sporicidal activity	
Methods employed	**AFNOR NF-T-72-231 and EN 13704** **(IBC = 10^8/10^7 cfu/ml R ≥ 3 log/R ≥ 5 log)**
Strains employed	*Bacillus subtilis.* ATCC 6633
results	**Contact time 10 minutes – Reduction > 5 log MRC = 0,05%**

LEGEND:
IMC/IBC = Initial microbial/bacterial charge / titre
R = Expected reduction of the bacterial charge
CFU = Colony forming units
MRC = Minimum recommended concentration

5. Uses

Sterilisation activity: 10 minutes at room temperature[EP(25±5°C)].
Sporicidal and high level disinfection: 5 minutes at room temperature [EP(25±5°C)]

Stability after activation: 15 days in covered trays. The number of cycles and the stability after activation will vary depending on the type of endoscope and endoscope reprocessor, the correct execution of the cleaning procedures provided by Guidelines and the **MRC** (minimum recommended concentration). Adaspor Plus Test Strips can confirm that the product is still above the peracetic acid **MRC** of 0,05%.

Directions for Use:
Pour first the content of Solution A and then of Solution B into a tray/basin or into the Automated Endoscope Reprocessor tank according to the manufacturer's instructions.
For manual disinfection: After washing and drying the load (medical devices) place it in the activated Adaspor Plus Ready To Use solution, making sure it penetrates all cavities, channels, etc. Remove disinfected devices using aseptic procedures and rinse them in sterile water before use.

For use in automated endoscope reprocessors and ultrasonic tubs: Fill containers with the required activated Adaspor™ Plus Ready To Use solution according to manufacturer instructions. Set the automated parameters in the automated reprocessor with the appropriate contact time.

The automated reprocessor will perform a rinse step at the end of the disinfection/sterilisation process.

Compatibility: The activated solution has been shown to be compatible with materials employed in the manufacturing of medical devices, especially endoscopes and automated endoscope reprocessors. Data is available from the manufacturer.

6. Toxicological information

Solution A	
DL_{50} oral on rats	1540 mg/kg
DL_{50} cutaneous on rats	1410 mg/kg
Inhalation (CL_{50})	450 mg/m^3

Solution B (Isazone™ and coformulants)
The composition does not require the use of any further precaution apart from the required ones: do not ingest, avoid direct prolonged contact. Isazone™, a component of Solution B, is part of a group of substances administered pharmacologically with oral medium doses of 100 mg once or twice a day. Skin contact with such substances has not shown any toxicity value.
Solution A + B
Acute toxicity of Adaspor™ Plus Ready To Use (activated solution) has been investigated on rats administering repeated doses of 2000 mg/Kg on skin. There have been no cases of death nor observation of clinical evidence related to the treatment. These results confirm that Adaspor™ Plus Ready To Use has no toxic effects if administered via dermal application on rats in a 24 H range at 2000 mg/Kg doses. The obsence of mortality indicates that its LD50 is even higher then the 2000 mg/kg dose. The latter in considered the NOEL dose (NO OBSERVED EFFECT LEVEL) for single oral doses. NOEL (No observed effect level) **2000 mg/kg**

7. Warnings

For hospital, medical and dental surgery use only. Solution A must be handled only by trained personnel, following appropriate safety procedures. Solution A and B can not be used separately.

Solution A (peracetic acid 5 %)

Warnings: **Hazard**

(H) Hazard statements
(H242) Heating may cause a fire.
(H290) May be corrosive to metals,
(H302) Harmful if swallowed.
(H314) Causes severe skin burns and eye damage.
(H335) May cause respiratory irritation
(H412) Harmful to aquatic organisms with long-term effects.
(P) Precautionary statements
(P210) Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
(P234) Keep only in original container.
(P260) Do not breathe vapours.
(P280) Wear protective gloves/protective clothing/eye protection/face protection, (face shield with helmet or face shield with goggles).
(P303+P361+P353) IN CASE OF CONTACT WITH THE SKIN (or with hair): take off immediately all contaminated clothing. Rinse skin with water/shower.
(P305+P351+P338) IF IN CONTACT WITH EYES: rinse throughly with water for several minutes. Remove any contact lenses if easy to do. Continue rinsing.
(P310) Immediately contact a local POISON CONTROL CENTER.
(P403+P235) Store in a cool, well-ventilated place.

Contains:
PERACETIC ACID
HYDROGEN PEROXIDE

Solution B (ISAZONE™ and coformulants)
Safety data sheet available on request for professional users.
(H) Hazard statements **/**
(P) Precautionary statements /

Keep away from children's reach. Store in a dry place at room temperature, away from heat sources.
Expiry date applies to properly preserved, unused product. Do not use after expiration date.
Do not dispose bottles in the environment after its use.
The activated and diluted product does not require particular precautionary measures for people and the environment.
After use, exhausted solutions should be reprocessed and disposed of according to existing legislation.

8. Physical and chimical characteristics

ADASPOR™ Plus Ready to Use	SOLUTIONS A+B
APPEARANCE	CLEAR LIQUID
COLOUR	CLEAR AND/OR SLIGHTLY YELLOW
SPECIFIC WEIGHT	1,00 ± 0,05
pH	5,0 ± 1,0
PERACETIC ACID	(0,18 – 0,23) %

The above data are referred to solutions after activation/dilution.

9. Quality control

Cantel Medical (Italy) S.r.l. operates in accordance to the Certified Quality System UNI EN ISO 9001–UNI CEI EN 13485.

10. Validity period

16 months for properly preserved, unused product.

15 days for activated/diluted solutions.

11. Preservation modalities

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

12. Capacity and material of containers

1 lt bottles, 5 lt tanks and tops are made of PE sealed in the ring top.

13. Name and address of Registered Trademark Owner and Distributor

Cantel Medical (Italy) S.r.l.
Via Laurentina, 169 Pomezia (Rome) – Italy
Phone + 39 – 06/9145399
Manufacturers

14. Compilation date

Ed.	Rev.	Data	Revision objective
1	0	30.09.2019	Change of Notified Body (CE0051)
	1	15.10.2019	Detailed disinfectant activity according to UNI EN 14885: 2019
	2	04.12.2020	Change to the expression of percentage formula of ingredient Isazone™. Mycobactericidal activity added to section 3 and update of section 5 “Directions for use” by extending stability after activation from 12 to 15 days. Alignment of phrase (P 280) with the TS in Italian.