Consultancy and Laboratory Services for Biomedical Quality

VALIDATION OF WASHER-DISINFECTOR

"MACCHINARIO DI SANIFICAZIONE AUSILI MOD. SANIFIKO S30"

REPORT N. 5779-17

Customer: **GIALDI S.R.L.**
Via Cantone, 99 - 42046 Reggiolo RE

TIME SCHEDULE

Acceptance N.:	17-5344
Samples receiving date:	10/11/2017
Start test date:	15/11/2017
End test date:	20/12/2017
Operators:	Dr. E. Viani

TEST LABORATORY
Coronati Consulting srl
Via L. Gavioli, 3 I-41037 Mirandola (MO)
Certified ISO 9001 /ISO 13485

Date	Prepared by: Dr. E. Viani	Verified and Approved by: Dr. Renzo Coronati
20/12/2017		

This test report is digitally signed by Dr. Renzo Giovanni Coronati
The digital signature has legal value according to Italian D. Lgs. 82/2005 and subsequent amendments.

Firmato digitalmente da RENZO GIOVANNI CORONATI

REFERENCE DOCUMENTS

- UNI CEN ISO/TS 15883-5:2006 “Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy ”
- Technical Procedure PT06 “Bioburden assessment”
- Testing Protocol PL151 “Validation of washer-disinfector of SANIFIKO S30”

PURPOSE

The purpose is to demonstrate the cleaning efficacy of washer-disinfectors (WD) according to the ISO 15883 series of standards.

SAMPLE IDENTIFICATION

Sample:	“MACCHINARIO DI SANIFICAZIONE AUSILI MOD. SANIFIKO S30”
Q.ty tested:	1
LOT	Serial n. 5

MEDICAL DEVICES SUBMITTED TO WASHING AND SANIFICATION

DEVICE N.1:	Deambulatore antibrachiale mod. D113 

DEVICE N.2-3-4-6-8:	Carrozzina mod. VENERE 

DEVICE N.5:	Carrozzina comoda mod. Selene Easy 

DEVICE N.7:	Carrozzina comoda mod. Saturnia 200 

INSTRUMENTS AND EQUIPMENTS

Laminar flow hood class ISO 5	ATR 001
Laminar flow hood class ISO 5	ATR 087
"Biohazard"laminar flow hood class ISO 5	ATR 046
Bacteriological Incubators	ATR 045, ATR 138, ATR 071
Water-bath	SS072
Balance	SS103
E. Faecium ATCC 27270	Cod. MS-E040 | Lot. 7111509
TSA (Tryptone Soya Agar)	Cod. 064PRB0013
WASH MED – Alkaline detergent for instruments and glass	Cod. 1126
SANIMED – Concentrated disinfectant	Cod. 1511
DRY MED – acid rinse agent detergent and descaler for medical automated washers	Cod. 1135
HemoCheck-S ™ kit (to detect blood residuals)	Cod:67067-12
Pyromol-Test ™ kit (to detect protein residuals)	Cod:67070-20
Human blood of a known donor (for blood residuals)	NA
Bovine Albumin (for protein residuals)	Cod. A2153-10G lot. SLBKV4150V
Mucin (Mucin from porcine stomach, type III)	Cod. M1778-10G lot. SLBV4979
Maize (Dextrin from maize starch)	Cod. 31410-100G lot. BCBS0910V

CYCLES AVAILABLE (ACCORDING TO THE MANUAL OF THE MACHINE)

Washing program (3, 5, 7 minutes)

The washing cycle is structured as follows (example based on the 3-minute washing program):
Phase 1 - Water loading
Clean water mixed with the detergent solution is loaded into the tank
Phase 2 - Cleaning
The load is sprayed using nozzles with hot water, in which the detergent solution is automatically mixed. The water occupies a collection tank from which the pump draws the liquid to spray the load using filters and nozzles.
Step 3 – Discharge
After the cleaning phase, the water is discharged into the waste water disposal pipe.
Phase 4: Filling
The machine is then recharged with clean water.
Phase 5 - Rinsing
Finally the load is nebulized with hot water, in which the rinsing solution is automatically mixed. The rinse guarantees a drying free of stains or residues of detergents.
After the rinsing phase, the water remains in the tank and is used for the next washing cycle.
The total duration of the 3-minute wash program is approx. 10 minutes, the minutes reported are related only to the cleaning phase.
The procedure of 5 and 7 minutes washing programs is identical, except for the cleaning phase that lasts 2 or 4 minutes longer. These programs can be used in case of stubborn stain.

For this validation 100 ml of WASH MED was used for each cycle.

Sanitation program

If clean water is already present in the collection tank, it proceeds directly with the sanification phase, otherwise the sanitization phase is preceded by the filling phase.
Phase 1 - Sanitization
The load is sprayed with hot water, in which the sanitizing solution is automatically mixed. The water occupies a collection tank from which the water pump collects the liquid to spray the load using filters and nozzles.
Phase 2 - Discharge
After the sanification phase, the water is discharged into the waste water disposal pipe.
Step 3: Filling
The machine is then refilled with clean water. If the float switch installed is faulty, the machinery switches off and signals an abnormal stop.
Phase 4 - Rinsing
Finally the load is nebulized with hot water, in which the rinsing solution is automatically mixed. The rinse guarantees a drying free of stains or residues of detergents.
The total duration of the sanitization program is 8 minutes.
The sanitization program can be activated during the wash cycle or separately. In the first case the sanitization starts immediately after the filling phase 4, in the second case the sanitization program proceeds as indicated in this paragraph.

For this validation 70 ml of SANIMED was used for each cycle.

Drying

The DRYING phase, if selected, is carried out at the end of the washing and / or sanitization programs. The process is carried out by means of the electric fans and the infrared lamps installed in the inner top of the washing chamber.

For this validation 100 ml of DRY MED was used for each cycle.

The cycles tested were 3 minutes washing program and the 7 minutes washing program. The only difference between the several washing program is the duration of the washing phase: if the 3 minutes washing program is validated, than is efficacious also the 5 minutes washing program.

OPERATING METHODS

VALIDATION OF METHOD FOR BIOBURDEN EVALUATION

Preparation of microbial suspension of inoculum of medical devices

The pellet containing the microorganism has been suspended in 10 ml of aqueous solution.
100 µl of the suspension have been plated on 5 Petri's dishes containing a suitable agar medium.
The dishes were incubated in condition reported in the table below.

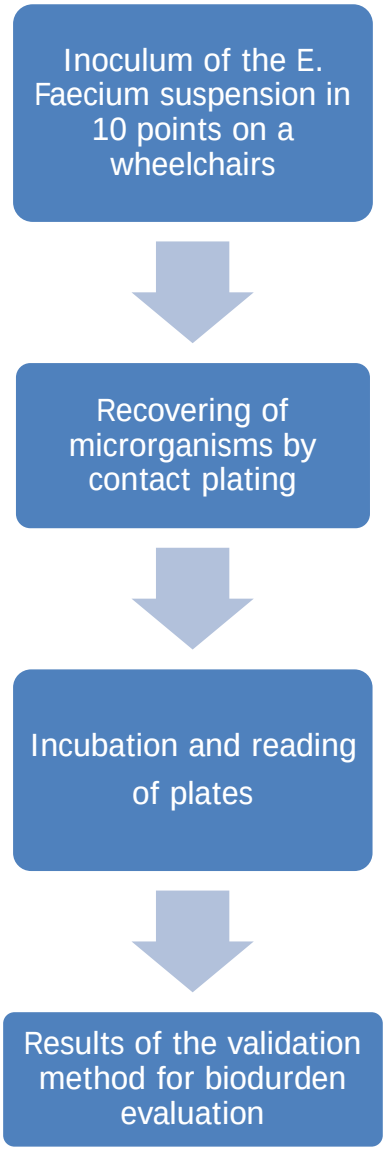
Microrganism	Abbr.	Medium	T °C	Period of incubation
E. FAECIUM	EF	TSA	35°C ± 2°C	48h

FLOW CHART OF THE STEPS

At the end of incubation the colonies have been collected and another suspension has been prepared.
A series of 1:10 dilution have been made to determine the concentration of the suspension.
The dilutions have been plated on suitable agar medium in duplicate.
At the end of incubation the colonies have been countered and the dilution of suspension having concentration of approximately 10^8 UFC/100µl has been determined.

Determination of recovery rate

FLOW CHART OF THE STEPS



MICROORGANISM INOCULUM

The purpose of this validation is to verify if the method used to estimate the microbiological contamination of a device is such as to allow adequate recovery of the microorganisms. The result of the validation is expressed as Recovery Rate.

In order to verify the cleaning, disinfection and sterilization microbial reduction process efficiency, each sample have been inoculated with E. Faecium.

For the inoculum with microoganisms wheelchairs have been used.

The contamination has been performed by inoculum of microorganism on the surface of the wheelchair. The inoculum was an aliquot of about 10^8 UFC/ device. This quantity was distributed on the surface. The wheelchairs have been dried.

DETERMINATION OF RECOVERY RATE

After the drying, each sample was submitted to contact plating with Petri dishes containing culture medium suitable to microorganism inoculated. At the end of the incubation the recovered C.F.U. (Colony-Forming Units) were counted. On the basis of inoculated and recovered microorganisms, corrective factor and recovery rate have been calculated in according to the PT06.

Acceptance criteria: $\geq 10^6$ UFC/device.

VALIDATION OF THE DETECTION LIMIT FOR TESTS TO DETECT BLOOD AND PROTEINS

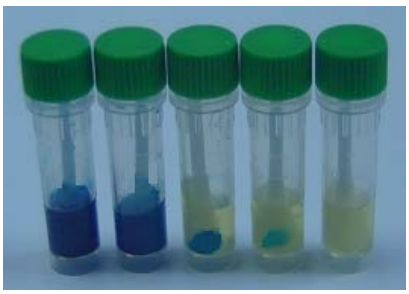
Blood residuals detection

The Hemocheck-S ™ kit was used to determine blood residuals on medical devices after the washing.
Due to the enzymatic peroxide reaction HemoCheck-S can detect smaller amount of blood residue than protein tests based on the Biuret reaction or Ninhydrin reaction. Another outstanding property of this forensic test is its sensitivity specific for blood residue, our major hygiene risk in the medical field. Sources of harmless residues like fingerprints will not give a positive result. There is no need for a long reaction time or a high reaction temperature which make HemoCheck-S especially easy to use giving immediate and safe results. HemoCheck-S can be used to check reprocessed surgical instruments and other surfaces whenever there is doubt that there could be blood residue left due to handling or processing problems.

Validation of the detection limit
100µl of fresh Blood was allowed to dry at room temperature for 2 hours.
Fresh human blood was diluted with demin. Water: 1:10, 1:100, 1:1000 and 1:10.000. 3.8µl of the 4 diluted samples gave approx.: 100µg, 10µg, 1µg and 0.1µg of dried blood.
The diluted blood was pipetted on a device. Sampling of the spots with a swab was used to validate the detection limits of HemoCheck-S for blood residues.

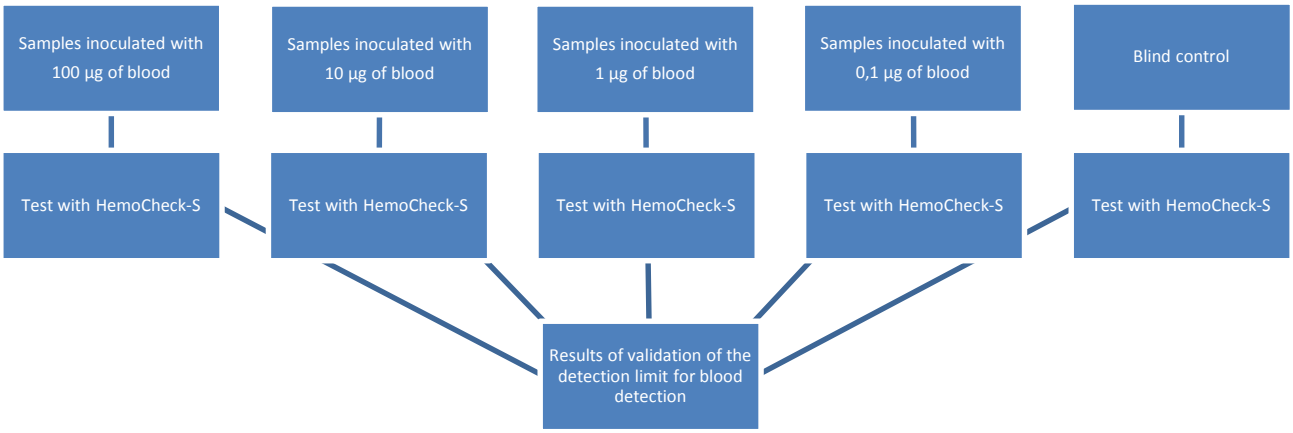
Results

Picture 2 shows the HemoCheck-S results for the dried blood samples (from left to right: 100µg, 10µg, 1µg, 0.1µg, Blind control). The Peroxidase reaction gave immediate results as shown in picture 2. All samples except the blind control gave positive result indicated by a colour change to blue. The high level of blood residue (100µg and 10 µg) even changed the indicator solution completely to blue. An additional 1:100.000 diluted blood sample was used to test 0.01µg of dried blood and did not give a positive result.



Picture 1

FLOW CHART OF THE STEPS



PROTEIN RESIDUALS DETECTION

The Pyromol-Test ™ kit was used to determine blood residuals on medical devices after the washing.

The Pyromol-Test is based on the formation of a protein-dye complex. This reaction detects the protein chain itself, therefore it can still show chemically altered and denaturated protein. This is mandatory for the detection of residue after chemical disinfection processes.

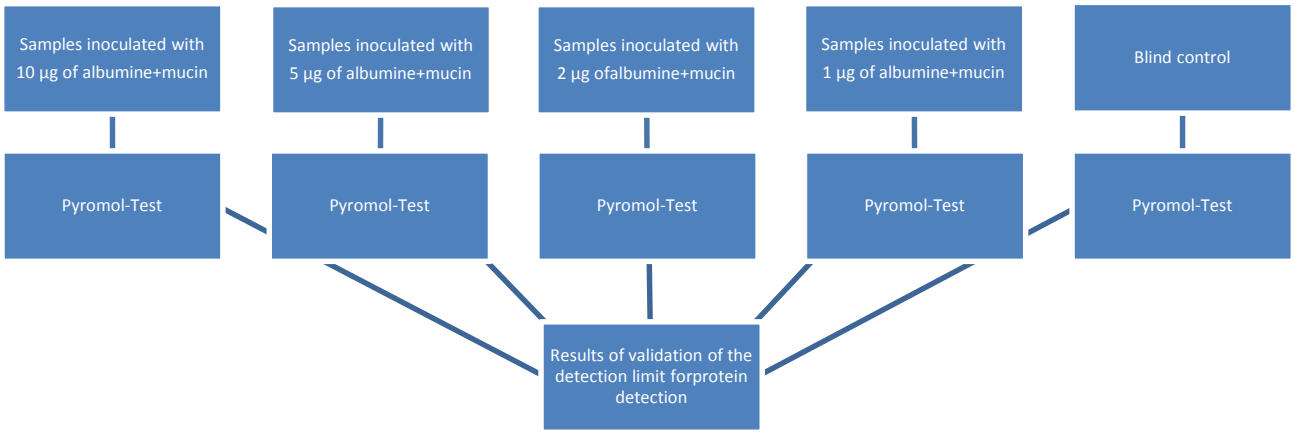
The detection limit of the Pyromol-Test was verified with a solution containing 3,0 g of mucin, 1,8 g di albumin and 9,0 g of maize starch into 200 ml of distilled water, according to Annex H ISO/TS 15883-5. A blind test without protein was performed.
The protein solution was diluted several times to obtained a solution with 10µg, 5µg, 2µg, 1µg of proteins.
The diluted solutions were pipetted on device. Sampling of the spots with a swab was used to validate the detection limits of Pyromol-Test ™ for protein residues.

Results

The Picture shows the Pyromol-Test results for the denaturated protein samples (from left to right: 10µg, 5µg, 2µg, 1µg, Blind control). All samples except the blind control gave a positive result indicated by the colour change to blue. While large amount of protein (> 5µg) shows a visible spot after 1 minute however, a 10 minutes waiting time is recommended to clearly detect small amount of protein. The protein samples chemically altered by glutaraldehyde and hyrogenperoxide gave corresponding results.

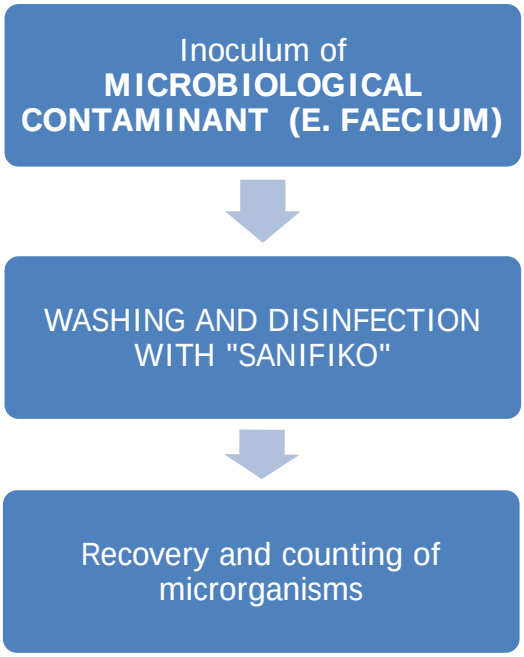
Picture 2

FLOW CHART OF THE STEPS



WASHING AND DISINFECTION EXECUTION AND EFFICIENCY ASSESSMENT IN REMOVING MICROBIOLOGICAL SOIL

FLOW CHART OF THE STEPS



Microorganisms inoculum

N. 4 carriage for disabled persons

The contamination has been performed by inoculation of the microorganisms on the surfaces of these medical devices. For each point of inoculum was inoculated 100 µl of an E. Faecium suspension of approx. 10^8 CFU. The devices have been left to dry with warm air.

Devices n.1 and 2 were washed with the 3 minutes washing program, while devices N.4-6 were submitted to the 7 minutes washing program.

Viable micro-organisms remained were recovered with plating to verify UFC reduction after the washing.

Acceptance criteria: reduction $\geq 10^5$ UFC/point of inoculum.

Device n.1	Points of inoculum 
Device n.2-3-4	Points of inoculum 

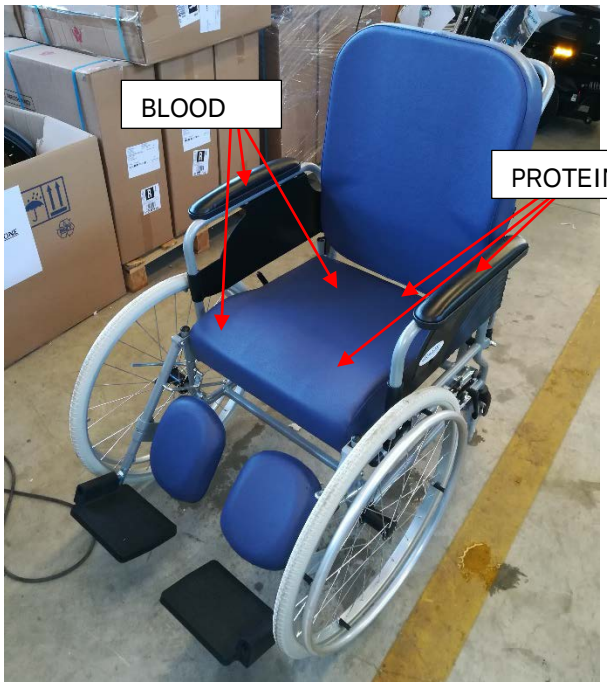
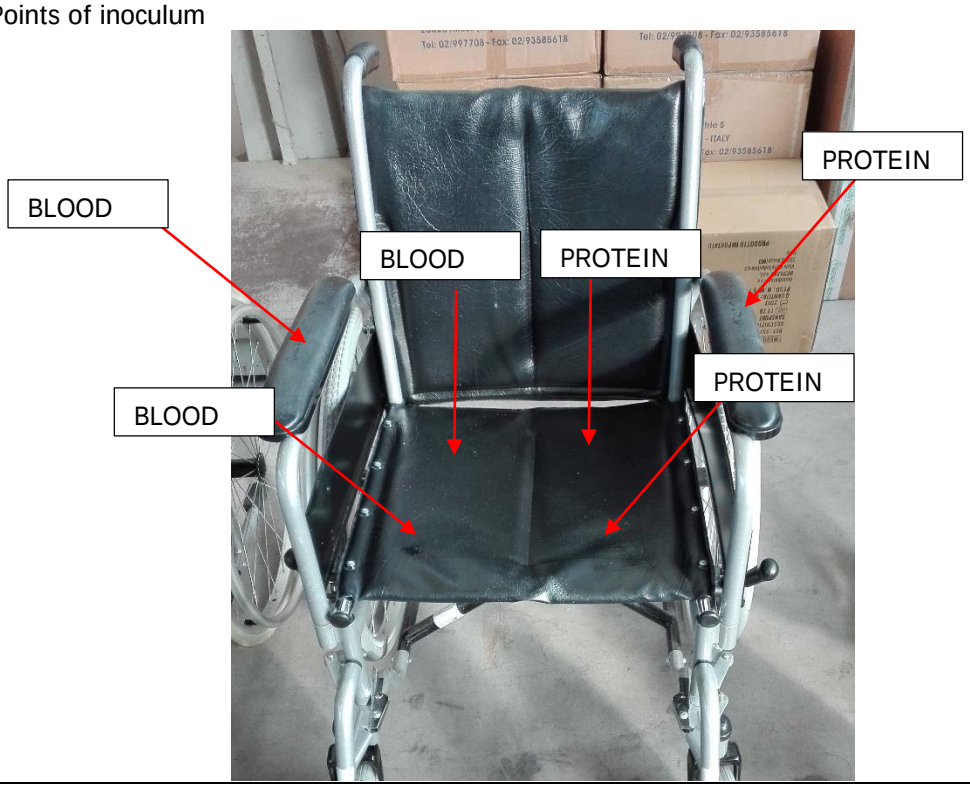
WASHING AND DISINFECTION EXECUTION AND EFFICIENCY ASSESSMENT IN REMOVING ORGANIC SOIL

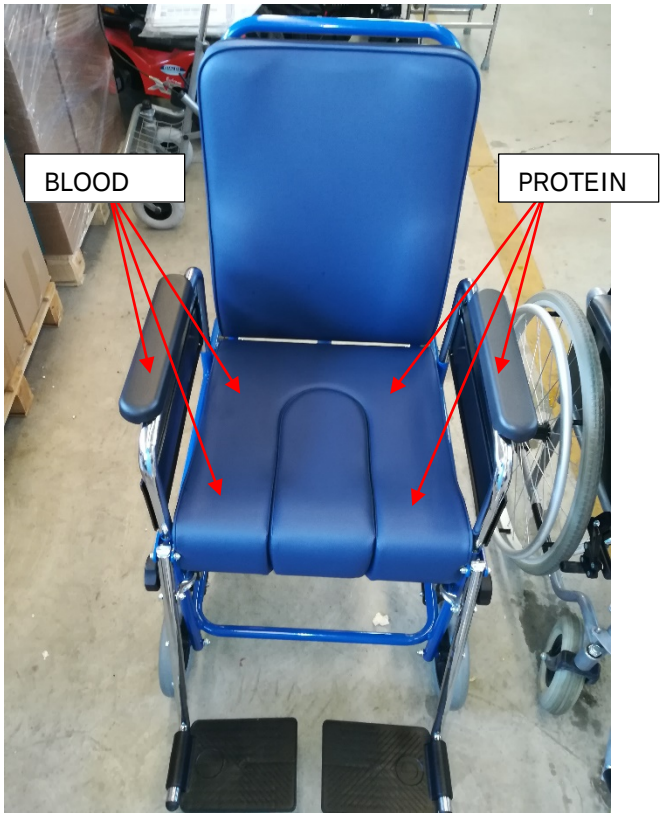
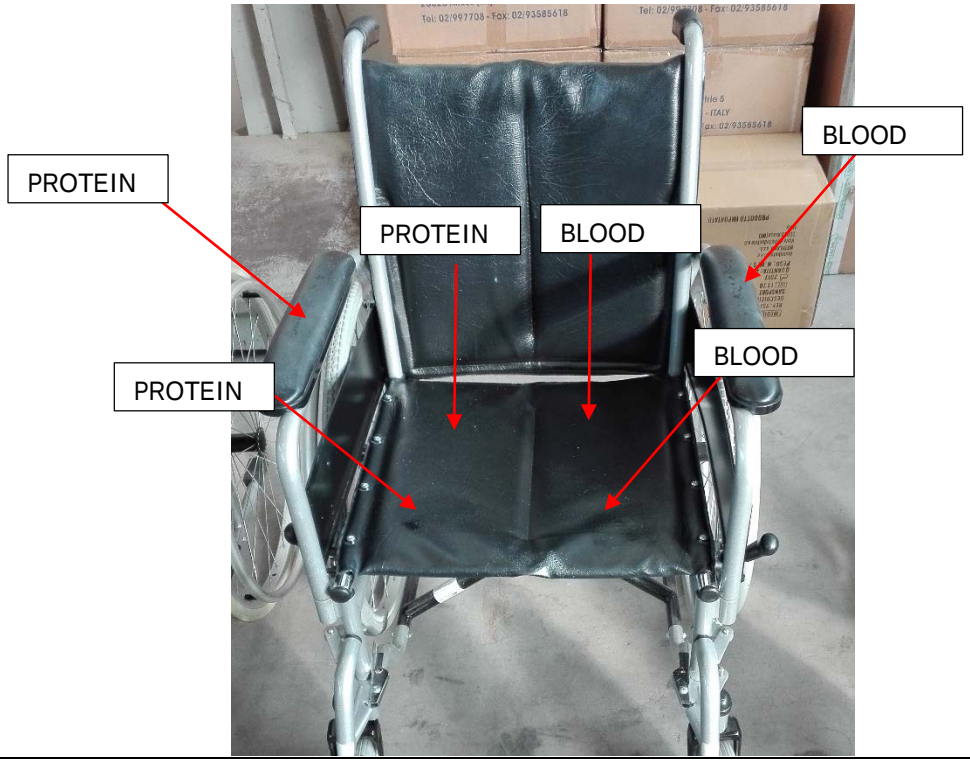
FLOW CHART OF THE STEPS

Organic soil inoculum

N. 4 carriage for disabled persons
On 4 devices (different from devices inoculated with microorganisms) it has been performed the inoculation of 100 µl blood (equal to 100 mg) and 100 µl of the protein solution (equal to 24 mg of proteins) prepared according to Annex H ISO/TS 15883-5. The soiling simulating has been distributed on the devices and left to dry at room temperature.

The devices contaminated with organic soil and subjected to the cleaning process were tested to detect the presence of residues with specific commercial kits.
Acceptance criteria: absence of visible stains (according to Annex H ISO/TS 15883-5) and absence of change of colour according to kit instructions (detection limits: 0,1 µg of blood, 1 µg of protein).

Device n.5	Points of inoculum 
Device n.6	Points of inoculum 

Device n.7	Points of inoculum 
Device n. 8	Points of inoculum 

RESULTS

VALIDATION OF METHOD FOR BIOBURDEN EVALUATION – DETERMINATION OF RECOVERY RATE		
	n. of CFU inoculated and n. of CFU recovered	
	EF	
	inoculum (average)	recovery (average)
1	80	22
2	80	23
3	80	22
4	80	25
5	80	19
6	80	22
7	80	22
8	80	27
9	80	16
10	80	18
Recovery Rate		27,0%
Corrective Factor		**3,7**

VALIDATION OF THE DETECTION LIMIT FOR TESTS TO DETECT BLOOD RESIDUALS HEMOCHECK-S										
	1		2		3		4		ctrl neg	
	inoculum	recovery	inoculum	recovery	inoculum	recovery	inoculum	recovery	inoculum	recovery
	100 ug of blood	colour change	10 ug of blood	colour change	1 ug of blood	colour change	0,1 ug of blood	colour change	no inoculum	no colour change
Result	Detection limit 0,1 ug of blood									

VALIDATION OF THE DETECTION LIMIT FOR TESTS TO DETECT PROTEIN RESIDUALS PYROMOL- TEST										
	1		2		3		4		ctrl neg	
	inoculum	recovery	inoculum	recovery	inoculum	recovery	inoculum	recovery	inoculum	recovery
	10 ug of albumine + mucin	colour change	5 ug of albumine + mucin	colour change	2 ug of albumine + mucin	colour change	1 ug of albumine + mucin	colour change	no inoculum	no colour change
Result	Detection limit 1 ug of albumin+mucin									

EFFICIENCY ASSESSMENT IN REMOVING MICROBIOLOGICAL SOIL					
Device	**Point of inoculum**	**UFC plated / point of inoculum**	**UFC recovered / point of inoculum**	**Reduction of UFC / point of inoculum**	**Reduction in log of UFC / point of inoculum**
1 (3 min. Washing Program)	**A**	170000000	4	10^8	8
	B	170000000	15	10^7	7
	C	170000000	41	10^7	7
	D	170000000	41	10^7	7
	E	170000000	19	10^7	7
	F	170000000	11	10^7	7
2 (3 min. Washing Program)	**A**	170000000	4	10^8	8
	B	170000000	111	10^6	6
	C	170000000	15	10^7	7
	D	170000000	11	10^7	7
	E	170000000	11	10^7	7
	F	170000000	11	10^7	7
3 (7 min. Washing Program)	**A**	170000000	7	10^7	7
	B	170000000	63	10	6
	C	170000000	11	10^7	7
	D	170000000	70	10^6	6
	E	170000000	15	10^7	7
	F	170000000	70	10^6	6
4 (7 min. Washing Program)	**A**	170000000	170	10^6	6
	B	170000000	141	10^6	6
	C	170000000	15	10^7	7
	D	170000000	41	10^7	7
	E	170000000	11	10^7	7
	F	170000000	15	10^7	7

EFFICIENCY ASSESSMENT IN REMOVING ORGANIC SOIL

Device after the inoculum and before the washing (3 MINUTES WASHING PROGRAM)

Device after the inoculum and after the washing (3 MINUTES WASHING PROGRAM)

Device after the inoculum and before the washing (3 MINUTES WASHING PROGRAM)

Device after the inoculum and after the washing (3 MINUTES WASHING PROGRAM)

Device after the inoculum and before the washing (7 MINUTES WASHING PROGRAM)

Device after the inoculum and after the washing (7 MINUTES WASHING PROGRAM)

Device after the inoculum and before the washing (7 MINUTES WASHING PROGRAM)

Device after the inoculum and after the washing (7 MINUTES WASHING PROGRAM)

Device	5		6		pos ctrl		neg ctrl	
Point of inoculum	inoculum	recovery	inoculum	recovery	inoculum	recovery	inoculum	recovery
A	100 mg of blood	no colour change	100 mg of blood	no colour change	100 mg of blood	colour change	no inoculum	no colour change
B	100 mg of blood	no colour change	100 mg of blood	no colour change				
C	100 mg of blood	no colour change	100 mg of blood	no colour change				
Result		Pass		Pass		Pass		Pass

EFFICIENCY ASSESSMENT OF 7 MINUTES WASHING PROGRAM CONTAMINATED WITH BLOOD HEMOCHECK-S TEST								
Device	7		8		pos ctrl		neg ctrl	
Point of inoculum	inoculum	recovery	inoculum	recovery	inoculum	recovery	inoculum	recovery
A	100 mg of blood	no colour change	100 mg of blood	no colour change	100 mg of blood	colour change	no inoculum	no colour change
B	100 mg of blood	no colour change	100 mg of blood	no colour change				
C	100 mg of blood	no colour change	100 mg of blood	no colour change				
Result		Pass		Pass		Pass		Pass

EFFICIENCY ASSESSMENT OF 3 MINUTES WASHING PROGRAM CONTAMINATED WITH PROTEIN (ALBUMIN+MUCIN) PYROMOL TEST								
Device	5		6		pos ctrl		neg ctrl	
Point of inoculum	inoculum	recovery	inoculum	recovery	inoculum	recovery	inoculum	recovery
D	24 mg of protein	no colour change	24 mg of protein	no colour change	24 mg of protein	colour change	no inoculum	no colour change
E	24 mg of protein	no colour change	24 mg of protein	no colour change				
F	24 mg of protein	no colour change	24 mg of protein	no colour change				
Result		Pass		Pass		Pass		Pass

EFFICIENCY ASSESSMENT OF 7 MINUTES WASHING PROGRAM CONTAMINATED WITH PROTEIN (ALBUMIN+MUCIN) PYROMOL TEST								
Device	7		8		pos ctrl		neg ctrl	
Point of inoculum	inoculum	recovery	inoculum	recovery	inoculum	recovery	inoculum	recovery
D	24 mg of protein	no colour change	24 mg of protein	no colour change	24 mg of protein	colour change	no inoculum	no colour change
E	24 mg of protein	no colour change	24 mg of protein	no colour change				
F	24 mg of protein	no colour change	24 mg of protein	no colour change				
Result		Pass		Pass		Pass		Pass

CONCLUSIONS

The “Macchinario di sanificazione ausili mod. SANIFIKO S30” meets the established acceptance criteria.

ANNEXES

Annex 01: Technical data sheet “WASH MED”
Annex 02: Technical data sheet “SANIMED”
Annex 03: Technical data sheet “DRY MED”

⇨The present test report refers only to the samples examined.

Coronati consulting lab

Consultancy and Laboratory Services for Biomedical Quality

WASH MED

SCHEDA TECNICA
TECHNICAL DATA SHEET

Detergente alcalino per strumentazione e vetreria

EN - Alkaline detergent for instruments and glass | **SL** - Alkalni detergent za instrumente in steklovino | **RO** - Detergent alcalin pentru instrumente şi sticlărie | **FR** - Nettoyant alcalin pour les instruments et la verrerie | **DE** -Alkalischer Reiniger für Instrumente und Glasgeräte | **ES** - Detergente alcalino para instrumental y cristalería

IT - Detergente per trattamento automatizzato di strumentario chirurgico, anche in alluminio anodizzato, vetreria da laboratorio, articoli per neonato e zoccoli da sala operatoria. **EN** - Detergent for automated reprocessing of surgical instruments, including anodized aluminium, laboratory glassware, neonatal items and operating theatre shoes. **SL** - Detergent za avtomatsko obdelavo kirurških instrumentov, tudi iz anodiziranega aluminija, laboratorijske steklovine, izdelkov za dojenčke in obutve za operacijske sobe. **RO** - Detergent pentru tratamentul automatizat al instrumentelor chirurgicale, inclusiv al celor din aluminiu anodizat, al sticlăriei de laborator, al articolelor pentru nou-născuţi şi al saboţilor medicali pentru sala de operaţie. **FR** - Nettoyant pour le traitement automatisé de l'ensemble des instruments chirurgicaux, même en aluminium anodisé, la verrerie de laboratoire, les articles pour nourrissons et les sabots de bloc opératoire. **DE** - Reinigung für die automatisierte Behandlung von chirurgischen Instrumenten auch aus eloxiertem Aluminium, Labor-Glasgeräten, Babyartikeln und Clogs für OP-Säle. **ES** - Detergente para el tratamiento automatizado de instrumental quirúrgico, incluso de aluminio anodizado, cristalería de laboratorio, artículos para recién nacidos y zuecos sanitarios para quirófanos.

IMPIEGO/MODO D'USO - USE/DIRECTIONS FOR USE

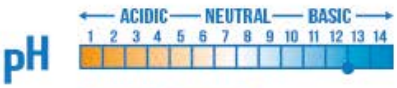
IT - IMPIEGO: In qualsiasi condizione di durezza dell'acqua. **MODALITA' D'USO:** detergente per macchine a prelievo automatico: inserire il pescante direttamente nella tanica. **EN - USE:** In any water hardness condition. **HOW TO USE:** Detergent for instrument washers with automatic dispensing: place the dip tube directly into the container. **SL - UPORABA:** Pri vseh trdotah vode. **NAVODILA ZA UPORABO:** Detergent za naprave s samodejnim odmerjanjem: sesalno cev vstavite neposredno v embalažo. **RO - FOLOSIRE:** Pentru orice grad de duritate a apei. **MOD DE UTILIZARE:** Detergent pentru maşinile cu sistem de dozare automat: introduceţi tubul de aspiraţie direct în recipientul cu produs. **FR - UTILISATION:** Quelle que soit la dureté de l'eau. **MODE D'EMPLOI:** nettoyant pour machines à prélèvement automatique: plongez le tuyau d'aspiration directement dans le bidon. **DE - ANWENDUNG:** Für jede Wasserhärte. **GEBRAUCHSANLEITUNG:** Reinigungsmittel für Maschinen mit automatischer Entnahme: Den Saugschlauch direkt in den Kanister einführen. **ES - USO:** Con cualquier tipo de dureza de agua. **MODO DE USO:** Detergente para máquinas con dosificación automática: introducir directamente el tubo de aspiración en el bidón.

DOSAGGIO - DOSAGE

IT - DOSAGGIO: detergente per macchine a prelievo automatico: 3-5 g per litro in funzione della durezza dell'acqua e del grado di sporco. **EN - DOSING:** Detergent for instrument washers with automatic dispensing: 3-5 g per litre according to water hardness and degree of soil. **SL - ODMEREK:** Detergent za naprave s samodejnim odmerjanjem: 3–5 g na liter, pri čemer se upošteva trdota vode in stopnja umazanosti. **RO - DOZARE:** Pentru maşini cu sistem de dozare automat: 3-5 g la un litru, în funcţie de duritatea apei şi gradul de murdărie. **FR - DOSAGE:** nettoyant pour machines à prélèvement automatique: 3-5 g par litre en fonction de la dureté de l'eau et de la saleté. **DE - DOSIERUNG:** Reinigungsmittel für Maschinen mit automatischer Entnahme: 3-5 g pro Liter entsprechend der Wasserhärte und der Verschmutzung. **ES - DOSIFICACIÓN:** Detergente para máquinas con dosificación automática: 3-5 g por litro dependiendo de la dureza del agua y del grado de suciedad.

COMPOSIZIONE CHIMICA - CHEMICAL COMPOSITION (REG. 648/2004/CE)

IT - COMPOSIZIONE CHIMICA: 5% - 15%: EDTA, < 5%: Tensioattivi non ionici. **EN - CHEMICAL COMPOSITION:** 5% - 15%: EDTA, < 5%: non-ionic surfactants. **SL - KEMIČNA SESTAVA:** 5% - 15%: EDTA, < 5%: neionske površinsko aktivne snovi. **RO - COMPOZIŢIE CHIMICĂ:** 5% - 15%: EDTA, < 5%: agenţi tensioactivi neionici, **FR - COMPOSITION CHIMIQUE:** 5% - 15%: EDTA, < 5%: agents de surface non ioniques. **DE - CHEMISCHE ZUSAMMENSETZUNG:** 5% - 15%: EDTA, < 5%: nichtionische Tenside. **ES - COMPOSICIÓN QUÍMICA:** 5% - 15%: EDTA, < 5%: tensioactivos no iónicos.



PROFESSIONAL

DISPOSITIVO MEDICO DI CLASSE I CONFORME ALLA DIRETTIVA 93/42/CE E SUCCESSIVE INTEGRAZIONI
N° REPERTORIO: 1508311/R
CLASSIFICAZIONE CND: V07

PROPRIETÀ FISICHE - PHISICAL PROPRIETIES	
STATO FISICO - APPEARANCE	LIQUIDO-LIQUID
COLORE - COLOR	GIALLO - YELLOW
ODORE - ODOUR	TECNICO / CARATTERISTICO - TECHNICAL / CHARACTERISTIC

PALLETTIZZAZIONE - PALLETIZATION			
CODICE - CODE	1126	PZ X CT - PCS X BOX	2
COD. EAN	8054633834800	CT X PLT - BOX X PLT	72
CONFEZIONE - PACK	5,5KG - 5L	CT X ST - BOX X LAYER	18

Coronati consulting lab

Consultancy and Laboratory Services for Biomedical Quality

SANIMED®

SCHEDA TECNICA
TECHNICAL DATA SHEET

PRESIDIO MEDICO CHIRURGICO - REGISTRAZIONE DEL MINISTERO DELLA SALUTE N. 20047

Disinfettante concentrato per uso ambientale

EN - Concentrated disinfectant for use in the environment | **FR** - Désinfectant concentré pour usage dans différents milieux | **ES** - Desinfectante concentrado ambiental

IT - SANIMED® detergente disinfettante concentrato, esplica un'azione fungicida e battericida, risultando attivo contro i batteri gram-positivi, gram-negativi, funghi e muffe, presenti negli ambienti domestici e professionali. SANIMED® è particolarmente adatto per disinfettare superfici e attrezzature del settore agro-alimentare, alberghiero e della ristorazione. E' idoneo anche per l'uso in ambienti molto frequentati, quali bagni di locali pubblici, ambulatori e ambienti ospedalieri. **EN** - SANIMED® concentrated disinfectant detergent provides a fungicidal and bactericidal action which is effective against gram-positive bacteria, gram-negative bacteria, fungi and moulds that are found in domestic and professional environments. SANIMED® is especially suited to disinfect surfaces and equipment in agri-food, hotel, and restaurant industries. It is also suitable for use in high foot-traffic areas such as public toilets, hospitals and outpatient clinics. **FR** - SANIMED® détergent désinfectant concentré exerce une action fongicide et bactéricide, agit contre les bactéries à Gram positif, à Gram négatif, les champignons et les moisissures présents dans les milieux domestiques et professionnels. SANIMED® est particulièrement adapté pour désinfecter les surfaces et les équipements du secteur agro-alimentaire, hôtelier et de la restauration. Il est également adapté à une utilisation dans des milieux très fréquentés comme les toilettes des lieux publics, les cliniques et les hôpitaux. **ES** - SANIMED® detergente desinfectante concentrado que, con su acción fungicida y bactericida protege contra las bacterias gram-positivas, gram-negativas, los hongos y mohos que se encuentran en los ambientes domésticos y profesionales. SANIMED® es ideal para desinfectar las superficies y equipamientos del sector agroalimentario, hotelero y de la restauración. Es ideal también para ambientes muy frecuentados, como baños de locales públicos, consultorios y ambientes hospitalarios.

IMPIEGO/MODO D'USO - USE/DIRECTIONS FOR USE

IT - MODALITÀ D'USO: Diluire SANIMED® in acqua e nebulizzare o stendere con spugna o mop. Per piccoli utensili immergere il materiale da disinfettare. Risciacquare dopo l'uso. **EN - HOW TO USE:** Dilute SANIMED® with water and spray or apply using a sponge or a mop. For small utensils, immerse the material to disinfect. Rinse after use. **FR - MODE D'EMPLOI:** Diluer SANIMED® dans de l'eau et pulvériser ou appliquer avec une éponge ou une serpillère. Pour les petits outils, plonger le matériel à désinfecter. Rincer après l'utilisation. **ES - MODO DE USO:** Diluya SANIMED® en agua y rocíe o extienda con una esponja o mopa. Para pequeños utensilios, sumerja directamente el material que se quiere desinfectar. Enjuague después de usar.

DOSAGGIO - DOSAGE

IT - DILUIZIONI D'USO: Per la normale pulizia diluire SANIMED® allo 0,5%, pari a 25ml per 5 litri d'acqua (circa ½ tappo). Risciacquare. Per la disinfezione diluire SANIMED® all' 1,5%, pari a 75ml per 5 litri d'acqua (circa 1 tappo e ½) e lasciare agire per almeno 15 minuti. Risciacquare. **ATTENZIONE** - La ditta produttrice non si assume alcuna responsabilità per eventuali danni a persone e cose che possono derivare da un uso improprio del formulato. Chi impiega il prodotto è responsabile anche nei confronti di terzi. **EN - DILUTIONS FOR USE:** For normal cleaning, dilute SANIMED® at 0.5%, which is equivalent to 25ml for every 5 litres of water (approximately ½ cap). Rinse. To disinfect, dilute SANIMED® at 1.5%, which is equivalent to 75ml for every 5 litres of water (approximately 1½ caps), and leave it to work for at least 15 minutes. Rinse. **ATTENTION** - The manufacturer is not liable for any damage to persons or property caused as a result of improper use of the product. Whoever uses the product is also responsible for third parties. **FR - PROPORTIONS DE DILUTION:** Pour le nettoyage ordinaire, diluer 0,5% de SANIMED® soit 25ml pour 5 litres d'eau (environ la moitié d'un bouchon). Rincer. Pour la désinfection, diluer 1,5 % de SANIMED® soit 75ml pour 5 litres d'eau (environ 1 bouchon et demi) et laisser agir pendant 15 minutes au moins. Rincer. **ATTENTION** - Le fabricant n'est pas responsable des dommages personnels et matériels pouvant résulter d'un usage impropre de la formule. Qui utilise le produit est également responsable à l'égard des tiers. **ES - DILUCIONES DE USO:** Para limpiar normalmente, diluya SANIMED® al 0,5%, igual a 25ml por 5 litros de agua (alrededor de ¼ tapa). Enjuague. Para desinfectar diluya SANIMED® al 1,5%, igual a 75ml por 5 litros de agua (alrededor de 1 tapa y ½) y deje actuar durante al menos 15 minutos. Enjuague. **CUIDADO** - El fabricante se exime de toda responsabilidad por posibles daños a personas y cosas que se deriven de un uso inadecuado de la fórmula. El usuario del producto asume la responsabilidad ante terceras personas.

AVVERTENZE - WARNINGS

IT - ATTENZIONE - La ditta produttrice non si assume alcuna responsabilità per eventuali danni a persone e cose che possono derivare da un uso improprio del formulato. Chi impiega il prodotto è responsabile anche nei confronti di terzi. Non contaminare durante l'uso alimenti, bevande, recipienti destinati a contenerne. Non associare ad altri prodotti dotati di azione disinfettante o a detergenti anionici. DA NON VENDERSI SFUSO. NON RIUTILIZZARE IL CONTENITORE. NON DISPERDERE IL CONTENITORE NELL'AMBIENTE DOPO L'USO. **EN - WARNING** - The manufacturer is not liable for any damage to persons or property caused as a result of improper use of the product. Whoever uses the product is also responsible for third parties. Avoid contamination of food, drinks and their containers during use. Do not mix with other disinfectants or anionic cleaners. DO NOT SELL IN BULK. DO NOT REUSE THE CONTAINER. DO NOT DISPOSE AS HOUSEHOLD WASTE AFTER USE. **FR - ATTENTION** - Le fabricant n'est pas responsable des dommages personnels et matériels pouvant résulter d'un usage impropre de la formule. Qui utilise le produit est également responsable à l'égard des tiers. Pendant l'utilisation, ne pas contaminer les aliments, boissons ou récipients devant en contenir. Ne pas associer à d'autres produits ayant une action désinfectante ou à des détergents anioniques. VENTE AU DÉTAIL INTERDITE. NE PAS RÉUTILISER LE RÉCIPIENT. NE PAS ABANDONNER LE RÉCIPIENT DANS LA NATURE APRÈS USAGE. **ES - CUIDADO** - El fabricante se exime de toda responsabilidad por posibles daños a personas y cosas que se deriven de un uso inadecuado de la fórmula. El usuario del producto asume la responsabilidad ante terceras personas. No contamine durante el uso alimentos, bebidas y recipientesdestinados a la conservación. No usar junto con otros productosque tengan acción desinfectante o con detergentes aniónicos. NO DEBE VENDERSE A GRANEL. NO REUTILICE EL ENVASE. NO ARROJE EL ENVASE EN EL MEDIO AMBIENTE DESPUÉS DEL USO.

COMPOSIZIONE CHIMICA - CHEMICAL COMPOSITION (REG. 648/2004/CE)

IT - COMPOSIZIONE: 100g di prodotto contengono: Alchil Dimetilbenzilammonio Cloruro g10, Coformulanti, Colore e Acqua q.b.a. g100. **EN** - COMPOSITION: 100g of product contain: Alkyl dimethyl benzyl ammonium chloride 10g. Coformulants, colouring and water as required at 100g. **FR** - COMPOSITION: 100g de produit contiennent: Alkyl diméthylbelzylammonium chlorure g10. Coformulants, colorants et eau quantum satis à 100g. **ES** - COMPOSICIÓN: 100 g de producto contienen: Cloruro de dialquil dimetil amonio 10g. Coadyuvantes, colorantes y agua c.s.p para 100g.

pH ACIDIC — NEUTRAL — BASIC
1 2 3 4 5 6 7 8 9 10 11 12 13 14

H.A.C.C.P.

PROFESSIONAL

IT - Validità: 2 anni a temperatura ambiente
EN - Validity: 2 years at room temperature
FR - Validité: 2 ans à température ambiante
ES - Validez: 2 años a temperatura ambiente

Officina di produzione:
ITALCHIMICA S.r.l. – 35127 Padova (PD)

PROPRIETÀ FISICHE - PHISICAL PROPRIETIES	
STATO FISICO - APPEARANCE	LIQUIDO-LIQUID
COLORE - COLOR	VERDE-GREEN
ODORE - ODOUR	CARATTERISTICO-CHARACTERISTIC

PALLETTIZZAZIONE - PALLETIZATION			
CODICE - CODE	1511	PZ X CT - PCS X BOX	2
COD. EAN	8032680351248	CT X PLT - BOX X PLT	72
CONFEZIONE - PACK	5KG - 5,0L	CT X ST - BOX X LAYER	18

Consultancy and Laboratory Services for Biomedical Quality

DRY MED

SCHEDA TECNICA
TECHNICAL DATA SHEET

Agente di risciacquo acido detergente e disincrostante per macchine di lavaggio ospedaliere

EN - Acid rinse agent detergent and descaler for medical automated washers. | **SL** - Detergent na osnovi kisline za izpiranje in odstranjevanje oblog za bolnišnične čistilne stroje | **RO** - Agent de clătire acid detergent şi dezincrustant pentru maşini de spălat instrumentar medical din spitale. | **FR** - Agent de rinçage acide nettoyant et détartrant pour machines de lavage des milieux hospitaliers | DE - Säurehaltiger fett- und kalklösender Spülzusatz für Krankenhaus-Spülmaschinen | **ES** - Agente de enjuague ácido detergente y desincrustante para máquinas lavadoras de hospitales

IT - Agente di risciacquo acido detergente, disincrostante e brillantante per macchine di lavaggio ospedaliere, con funzioni di antialone ed elimina odori. Non aggredisce nè plastiche nè altri articoli termolabili. **EN** - Acid rinse agent detergent, descaler and rinse aid for medical automated washers, with anti-streak and odour eliminator function. Does not attack plastics or other objects prone to heat damage. **SL** - Detergent na osnovi kisline za izpiranje, odstranjevanje oblog in loščenje za bolnišnične čistilne stroje, ki preprečuje nastanek madežev in odpravlja neprijetne vonjave. Ne poškoduje plastike in drugih na toploto občutljivih izdelkov. **RO** - Agent de clătire acid detergent şi dezincrustant pentru maşini de spălat instrumentar medical din spitale. Nu lasă urme şi elimină mirosurile neplăcute. Nu atacă articolele din plastic sau alte materiale sensibile la căldură. **FR** - Agent de rinçage acide nettoyant, détartrant et liquide de rinçage pour machines de lavage des milieux hospitaliers, avec fonction anti-traces et destructeur d'odeurs. Il n'agresse ni les plastiques ni les autres instruments thermolabiles. **DE** - Säurehaltiger fett- und kalklösender Klarspülzusatz für Krankenhaus-Spülmaschinen mit Funktion streifenfreier Glanz und Geruchsneutralisierer. Greift weder Kunststoff noch thermolabile Artikel an. **ES** - Agente de enjuague ácido detergente, desincrustante y abrillantador para máquinas lavadoras de hospitales, no deja halos residuales y elimina los olores. No agrede ni el plástico ni otros artículos termolábiles.

IMPIEGO/MODO D'USO - USE/DIRECTIONS FOR USE

IT - IMPIEGO: In qualsiasi condizione di durezza dell'acqua. **MODALITA' D'USO:** Introdurre il prodotto nell'apposita vaschetta. Per sistemi a prelievo automatico: immergere il pescante direttamente nella tanica. **EN - USE:** In any water hardness condition. **HOW TO USE:** pour product into the dispenser. For automatic dosing systems: place the dip tube directly into the container. **SL - UPORABA:** Pri vseh trdotah vode. **NAVODILA ZA UPORABO:** Izdelek nalijte v ustrezno posodico. Sistemi za samodejno doziranje: sesalno cev vstavite neposredno v embalažo. **RO - FOLOSIRE:** Pentru orice grad de duritate a apei. **MOD DE UTILIZARE:** turnaţi produsul în compartimentul respectiv. Pentru sisteme de dozare automate: introduceţi tubul de aspiraţie direct în recipientul cu produs. **FR - UTILISATION:** Quelle que soit la dureté de l'eau. **MODE D'EMPLOI:** versez le produit dans le compartiment qui lui est réservé. Pour les systèmes à prélèvement automatique : plongez le tuyau d'aspiration directement dans le bidon. **DE - ANWENDUNG:** Für jede Wasserhärte. **GEBRAUCHSANLEITUNG:** Das Produkt in die Dosierkammer geben. Systeme mit automatischer Entnahme: Den Saugschlauch direkt in den Kanister einführen. **ES - USO:** Con cualquier tipo de dureza de agua. **MODO DE USO:** introducir el producto en el compartimento correspondiente. Para sistemas de dosificación automática: introducir directamente el tubo de aspiración en el bidón.

DOSAGGIO - DOSAGE

IT - DOSAGGIO: 0,2g - 0,5g per litro in funzione alla durezza dell'acqua. **EN - DOSING:** 0.2-0.5 g per litre according to water hardness. **SL - ODMEREK:** 0,2 g - 0,5 g na liter, pri čemer se upošteva trdota vode. **RO - DOZARE:** 0,2g - 0,5g la un litru, în funcţie de duritatea apei. **FR - DOSAGE:** 0,2g - 0,5g par litre en fonction de la dureté de l'eau. **DE - DOSIERUNG:** 0,2-0,5g pro Liter je nach Wasserhärte. **ES - DOSIFICACIÓN:** 10,5g por litro dependiendo de la dureza del agua.

COMPOSIZIONE CHIMICA - CHEMICAL COMPOSITION (REG. 648/2004/CE)

IT - COMPOSIZIONE CHIMICA: 5% - 15%:Tensioattivi non ionici. Altri componenti: Conservante (Methylisothiazolinone, Benzisothiazolinone). **EN - CHEMICAL COMPOSITION:** 5% - 15%: non-ionic surfactants. Other components: Preservatives (Methylisothiazolinone, Benzisothiazolinone). **SL - KEMIČNA SESTAVA:** 5% - 15%: neionske površinsko aktivne snovi. Druge komponente: Konzervansi (Methylisothiazolinone, Benzisothiazolinone). **RO - COMPOZIŢIE CHIMICĂ:** 5% - 15%: agenti tensioactivi neionici, Alte componente: Conservanţi (Methylisothiazolinone, Benzisothiazolinone). **FR - COMPOSITION CHIMIQUE:** 5% - 15%: agents de surface non ioniques. Autres éléments: Conservateurs (Methylisothiazolinone, Benzisothiazolinone). **DE - CHEMISCHE ZUSAMMENSETZUNG:** 5% - 15%: nichtionische Tenside. Sonstige bestandteile: Konservierungsstoffe(Methylisothiazolinone, Benzisothiazolinone). **ES - COMPOSICIÓN QUÍMICA:** 5% - 15%: tensioactivos no iónicos. Otros componentes: Conservantes (Methylisothiazolinone, Benzisothiazolinone).

PROFESSIONAL

DISPOSITIVO MEDICO DI CLASSE I CONFORME ALLA DIRETTIVA 93/42/CE E SUCCESSIVE INTEGRAZIONI
N° REPERTORIO: 1508313/R
CLASSIFICAZIONE CND: V07

PROPRIETÀ FISICHE - PHISICAL PROPRIETIES	
STATO FISICO - APPEARANCE	LIQUIDO-LIQUID
COLORE - COLOR	BLU-BLUE
ODORE - ODOUR	TECNICO / CARATTERISTICO - TECHNICAL / CHARACTERISTIC

PALLETTIZZAZIONE - PALLETIZATION			
CODICE - CODE	1135	PZ X CT - PCS X BOX	2
COD. EAN	8054533831694	CT X PLT - BOX X PLT	72
CONFEZIONE - PACK	5,1KG - EL	CT X ST - BOX X LAYER	18