Elementary & Efficient Smart Sales Solutions

European Enterprise for Sani Sim System

Dimensione Service

Section 18	CLINICAL EVALUATION - BIOCIDAL EFFECTIVENESS

18. Clinical evaluation

The new essential requirement of Directive 93/42 / EC (6 a) states:

"Demonstration of compliance with the essential requirements must include a clinical evaluation in accordance with Annex X"

Our organization, in Annex X, applies art. 1.1-quinquies guaranteeing the performance elements as the action of the device is not directed to the patient but only to the environment and the medical devices contained therein.

The application of MEDDEV 2.7.1 rev. Is not considered 4 for the clinical evaluation but only performance part.

This evidence is justified by a careful evaluation carried out in Annex 4 "Risk Analysis".

Disinfection example

Coliform Sample, before processing

Samples after treatment with SANISIM Solution

The evaluation of clinical data is intended to ascertain the effectiveness of the combined disinfection system consisting of a nebulization device (SANISIM DM) which uses only the 6% hydrogen peroxide and silver ion solution (SANISIM SOLUTION).

This evaluation generally concerns the field of environmental sanitization in order to prevent and prevent the onset and development of infections caused by the presence of bacteria or similar pathogens, and in particular it concerns a medical device, the sanitizer DM SANISIM , capable of spreading and nebulizing a suitable sanitizing solution based on 6% hydrogen peroxide with silver nitrate, SANISIM SOLUTION.

We underline that the combined system for environmental sanitization SANISIM, which includes precisely equipment for spraying a specific disinfectant product, developed through a research activity that involved an important part of experimentation and which had as a context of reference is the healthcare sector, in which - as is known - infections constitute a problem of fundamental importance from various points of view (ethical, economic, safety).

To get an idea of the relevance of this problem, it is enough to consider that the infections that occur within hospital facilities cause more deaths per year than that caused by road accidents.

Therefore, in order to contrast, prevent and prevent the development of such infections, it is essential to use methods, systems, equipment, such as that subject of this evaluation, aimed at reducing the bacterial, viral and mycotic load in the rooms and in the premises. interested, and in particular, in hospitals, with the help of specific disinfectant products.

In the current technique, various types of machines, equipment, systems and systems in general are already present and in use for some time to carry out environmental sanitization through the use of specific disinfectant products sprayed and diffused in the environments concerned.

However, it is noted that both the traditional sanitization and disinfection systems and methods, and the respective nebulization systems of the disinfectant substance, and the specific sanitizing substances, despite their consolidated application, have numerous limits and drawbacks.

In particular, from the point of view of efficacy and efficiency, these known sanitization systems do not always allow to easily and effectively reach all the surfaces to be treated, especially the

hidden ones, which therefore can become a reservoir of bacteria and microorganisms, and therefore potential cause of infections.

Furthermore, the misting systems currently used are usually based on the wet misting of sanitizing and disinfectant products, with the drawback that in this way there is a certain environmental impact and the treated surfaces are left wet.

Furthermore, these known misting systems generally require that the rooms treated are of the sealed type, which entails long times, after having carried out the disinfection, before the rooms are usable again.

Furthermore, from the safety point of view, the known and in-use systems have the significant limitation of being operator-employees, or of requiring the use of personnel, thus exposing them to multiple risks, such as that of inhalation of irritating products.

Our disinfection system of SANISIM non-invasive medical devices, being inserted in the current context as outlined above and therefore having as a reference the needs to prevent and prevent the occurrence of bacterial infections in the most effective way, has the primary purpose of proposing and implementing a SANISIM DM device for environmental disinfection which constitutes a substantial improvement over the systems currently known and in use, and in particular offers better performance and results in terms of effectiveness for disinfecting the environments and surfaces concerned, and is also characterized by a fully automatic operation, so as to relieve the operator of any manual operation.

A second purpose of our SANISIM disinfection system, however connected to the previous one, is to define a new SANISIM SOLUTION disinfectant solution which is characterized by greater efficacy than the solutions currently known, to be used in combination with the SANISIM DM device so as to create a combined system for environmental sanitization, which offers significantly better and more effective performance than traditional systems, supported in an incontrovertible and objective way by appropriate experimental tests.

In summary, the guiding idea behind the SANISIM disinfection system is to create a medical device for environmental sanitization which has been given the trade name of SANISIM DM, which is automated, more effective, safer, more practical to use. use and imply shorter sanitization times than those obtainable with the already known and commercially available sanitization systems.

In particular, thanks to the use of a new disinfectant solution which has been given the name of SANISIM SOLUTION, which in turn exhibits greater efficacy and better performance than the currently known sanitizing solutions and compositions, sprayed in the form of micro-drops or dry fog, which has the characteristic and the advantage of not wetting.

As already pointed out, the SANISIM DM + SANISIM SOLUTION combined disinfection system has been developed and developed through a series of in-depth tests and experimental checks which have confirmed its innovative features and performances and the relevant advantages.

These tests, carried out at accredited centres and laboratories, were aimed at experimentally evaluating the biocidal activity of the SANISIM SOLUTION, both with reference to applicable sector standards and by extrapolation from literature data.

Below are some clinical studies that have demonstrated the effectiveness of treatment with hydrogen peroxide in contaminated healthcare environments:

- Shapey et. Al, JHI Oct 2008 (C.diff);
- *Bartels et al, JHI May 2008 (MRSA);*
- *Roques, C, EID 2010 (VRE);*
- *Barbut et al, ECCMID April 2008 (C.diff);*
- *Marty et al, tbp JHI (multiple pathogens);*
- *Andersen et al, JHI 2006 (eradication);*
- *Grare et al, JCM, 2008 (Mic.Tub).*

Published reports attribute good germicidal activity to hydrogen peroxide and attest to its bactericidal, virucidal, sporicidal activity and its fungicidal properties.[1]

Hydrogen peroxide is active against a wide range of microorganisms, including bacteria, yeasts, fungi, viruses, spores. [2]

The bactericidal and virucidal activity of hydrogen peroxide stabilized at 0.5% in a contact time of 1 minute and mycobactericidal activity in a contact time of 5 minutes has also been demonstrated.[3]

Bactericidal efficacy and stability of hydrogen peroxide in urine have been demonstrated against a variety of associated health pathogens; for organisms with high cellular catalase activity (e.g. S. aureus, S. marcescens and Proteus mirabilis) 30-60 minutes of exposure to 0.6% hydrogen peroxide are required for a 108 reduction in the number of cells, while for organisms with lower catalase activity (e.g. E. coli, Streptococcus species and Pseudomonas species) need only 15 minutes of exposure.[4]

In a survey of 3%, 10% and 15% hydrogen peroxide to reduce bacterial populations, a complete killing of 106 spores (i.e., Bacillus species) was demonstrated with a concentration of 10% and an exposure time 60 minutes. A 3% concentration for 150 minutes killed 106 spores in six of the seven exposure tests. [5]

A 10% hydrogen peroxide solution resulted in a 103 reduction in B. spore atrophaeus, and a> 105 decrease when tested against 13 other pathogens in 30 minutes at 20 ° C. [6]

Other studies have shown the antiviral activity of hydrogen peroxide against rhinovirus. [7]

The time to inactivate three rhinovirus serotypes using a 3% hydrogen peroxide solution is 6-8 minutes.

The mycobactericidal activity of 7.5% hydrogen peroxide was confirmed in a study that indicated the inactivation of> 105 multi-resistant M. tuberculosis after a 10-minute exposure. [8]

Thirty minutes were required to inactivate> 99.9% poliovirus and HAV. [9]

The 3% and 6% hydrogen peroxide was able to inactivate HAV in 1 minute in a carrier test. [10]

In one study, 6% hydrogen peroxide was more effective in high-level disinfection of flexible endoscopes than the 2% glutaraldehyde solution. [11]

Under normal conditions, hydrogen peroxide is extremely stable properly stored (for example, in dark containers). Decomposition or power loss in small containers is less than 2% per year at room temperature. [12]

Specifically, the bactericidal activity of SANISIM SOLUTION carried out towards Gram-positive, Gram-positive antibiotic resistant, Gram-negative and Gram-negative antibiotic resistant was evaluated experimentally as per the following table and with reference to specific sector standards.

Reference Bibliography

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3) Omidbakhsh N, Sattar SA. Broad-spectrum microbicidal activity, toxicologic assessment, and materials compatibility of a new generation of accelerated hydrogen peroxide-based environmental surface disinfectant. Am. J. Infect. Control 2006;34:251-7.

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12) *Anonymous. Hydrogen peroxide, ACS reagent*. Vol. 2001: Sigma Product Information Sheet, http://www.sigma.sial.com/sigma/proddata/h0904.htm.

Table 1: effectiveness tests phase 1 - English

Activity	Strain	Concentration of micro-organisms	Concentration of product used	Microorganism reduction obtained
Bactericide for pathogenic bacteria, positive coagulases, gram positive	Staphylococcus aureus ATCC 25923	10^5 ufc/ml	≤6% Hydrogen peroxide + silver ions	$5Log_{10}$
Bactericide for coagulase positive pathogenic bacteria, gram positive	Staphylococcus aureus ATCC 25923	10^5 ufc/ml	≤3% Hydrogen peroxide + silver ions	$2,5Log_{10}$
Bactericidal for bacteria of fecal origin, gluconidase positive, gram-negative	Escherichia coli ATCC 25922	10^5 ufc/ml	≤6% Hydrogen peroxide + silver ions	$5Log_{10}$
Bactericide for bacteria of faecal origin, gluconidase positive, gram-negative	Escherichia coli ATCC 25922	10^5 ufc/ml	≤3% Hydrogen peroxide + silver ions	$2,5Log_{10}$
Bactericidal, Gram-negative, positive oxidase, predominantly pulmonary pathogen	Pseudomonas aeruginosae ATCC 27853	10^5 ufc/ml	≤6% Hydrogen peroxide + silver ions	$5Log_{10}$
Bactericidal, Gram-negative, positive oxidase, predominantly pulmonary pathogen	Pseudomonas aeruginosae ATCC 27853	10^5 ufc/ml	≤3% Hydrogen peroxide + silver ions	$2,5Log_{10}$
Bactericide for pathogenic bacteria, coagulase positive, gram positive, antibiotic resistant	Staphylococcus aureus MRSA ATCC 43300	10^5 ufc/ml	≤6% Hydrogen peroxide + silver ions	$5Log_{10}$
Bactericidal, faecal origin, gram positive, resistant to extreme environmental conditions, antibiotic resistant	Enterococcus faecalis VRE ATCC 51299	10^5 ufc/ml	≤6% Hydrogen peroxide + silver ions	$5Log_{10}$
Bactericidal, nosocomial pathogen, resistant in the environment,	Acinetobacter baumannii ATCC 19606	10^5 ufc/ml	≤6% Hydrogen peroxide + silver ions	$5Log_{10}$
Bactericidal, Gram-negative, pathogen for immune-compromises, increasing antibiotic resistance	Klebsiella pneumoniae ATCC 700603	10^5 ufc/ml	≤6% Hydrogen peroxide + silver ions	$5Log_{10}$

PHASE 2 DATA - Step 1

Quantitative test tests were performed in the laboratory to evaluate the bactericidal activity of Sanisim Solution. Each strain was tested with the product, diluted to three different concentrations with water and under simulated dirt conditions in the laboratory, for a contact time of 5 minutes and at a constant temperature of 20°C.

The results obtained are:

Table 2: effectiveness tests phase 2-step 1 - English

Activity	Method protocol to be tested	Species	Microorganism concentration	Abatement found as a function of the concentration of diluted Sanisim Solution and in dirty conditions		
				6% with silver ions	3% with silver ions	1% with silver ions
Bactericide for pathogenic bacteria, positive coagulases, gram positive	EN 13727:2014 EN 14348:2005 EN 13704:2005	Staphylococcus aureus ATCC 25923	10^5 ufc/ml	$5Log_{10}$	$3\ Log_{10}$	$1,5Log_{10}$
Bactericide for bacteria of faecal origin, gluconidase positive, gram-negative	EN 13727:2014 EN 14348:2005 EN 13704:2005	Escherichia coli ATCC 25922	10^5 ufc/ml	$5Log_{10}$	$3Log_{10}$	$1,5Log_{10}$
Bactericidal, Gram-negative, positive oxidase, predominantly pulmonary pathogen	EN 13727:2014 EN 14348:2005 EN 13704:2005	Pseudomonas aeruginosae ATCC 27853	10^5 ufc/ml	$5Log_{10}$	$3\ Log_{10}$	$1,5Log_{10}$
Bactericide for pathogenic bacteria, coagulase positive, gram positive, antibiotic resistant	EN 13727:2014 EN 14348:2005 EN 13704:2005	Staphylococcus aureus MRSA ATCC 43300	10^5 ufc/ml	$5Log_{10}$	$2,5Log_{10}$	$0,5Log_{10}$
Bactericidal, faecal origin, gram positive, resistant to extreme environmental conditions, antibiotic resistant	EN 13727:2014 EN 14348:2005 EN 13704:2005	Enterococcus faecalis VRE ATCC 51299	10^5 ufc/ml	$5Log_{10}$	$2,5Log_{10}$	$0,5Log_{10}$
Bactericidal, nosocomial pathogen, environmentally resistant, antibiotic resistant	EN 13727:2014 EN 14348:2005 EN 13704:2005	Acinetobacter baumannii ATCC 19606	10^5 ufc/ml	$5Log_{10}$	$3\ Log_{10}$	$1,5Log_{10}$
Bactericidal, Gram-negative, pathogen for immune compromise, increasing antibiotic resistance	EN 13727:2014 EN 14348:2005 EN 13704:2005	Klebsiella pneumoniae ATCC 700603	10^5 ufc/ml	$5Log_{10}$	$3\ Log_{10}$	$1,5Log_{10}$

PHASE 2 DATA - Step 2

The first part of phase 2 took place in the laboratory. A test suspension of each bacterium, mixed with a solution of interfering substances, was inoculated on two stainless steel surfaces and dried. On a surface, a prepared sample of the Sanisim Solution product was applied, diluted in water, so as to cover the dried film. On the other surface, only water was deposited. The contact on both surfaces took place for 5 minutes at 20 ° C. Subsequently both surfaces were immersed in a neutralization solution so that the action of the disinfectant was immediately neutralized. The bacterial suspension was recovered from each surface and its viability was quantitatively assessed.

The results obtained are:

Table 3: effectiveness tests phase 2-step 2 (part 1) - English

Activity	Method protocol to be tested	Species	Microorganism concentration	Bacteria removal on the surface after 5 minutes of contact at 20°C in dirty conditions	
				Water	6% con ioni di argento
Bactericide for pathogenic bacteria, positive coagulases, gram positive	EN 13697:2005 EN 14561:2009 EN 14562:2009 EN 14563:2009	Staphylococcus aureus ATCC 25923	10^5 ufc/ml	$1Log_{10}$	$5Log_{10}$
Bactericide for bacteria of faecal origin, gluconidase positive, gram-negative	EN 13697:2005 EN 14561:2009 EN 14562:2009 EN 14563:2009	Escherichia coli ATCC 25922	10^5 ufc/ml	$1Log_{10}$	$5Log_{10}$
Bactericidal, Gram-negative, positive oxidase, predominantly pulmonary pathogen	EN 13697:2005 EN 14561:2009 EN 14562:2009 EN 14563:2009	Pseudomonas aeruginosae ATCC 27853	10^5 ufc/ml	$1Log_{10}$	$5Log_{10}$
Bactericide for pathogenic bacteria, coagulase positive, gram positive, antibiotic resistant	EN 13697:2005 EN 14561:2009 EN 14562:2009 EN 14563:2009	Staphylococcus aureus MRSA ATCC 43300	10^5 ufc/ml	$1Log_{10}$	$5Log_{10}$
Bactericidal, faecal origin, gram positive, resistant to extreme environmental conditions, antibiotic resistant	EN 13697:2005 EN 14561:2009 EN 14562:2009 EN 14563:2009	Enterococcus faecalis VRE ATCC 51299	10^5 ufc/ml	$1Log_{10}$	$5Log_{10}$
Bactericidal, nosocomial pathogen, environmentally resistant, antibiotic resistant	EN 13697:2005 EN 14561:2009 EN 14562:2009 EN 14563:2009	Acinetobacter baumannii ATCC 19606	10^5 ufc/ml	$1Log_{10}$	$5Log_{10}$
Bactericidal, Gram-negative, pathogen for immune compromise, increasing antibiotic resistance	EN 13697:2005 EN 14561:2009 EN 14562:2009 EN 14563:2009	Klebsiella pneumoniae ATCC 700603	10^5 ufc/ml	$1Log_{10}$	$5Log_{10}$

In the second part, the experiments of all the bacteria considered were actually carried out on site, in two different environments using two nebulizer devices: the Sanisim system lot: 01/14, Serial Number: SIM 02 and the SANISIMini system lot: 01/14 , Serial Number: SIM 01. In both cases, the disinfectant activity of the Sanisim Solution product, based on hydrogen peroxide at ⩽6% and silver ions, obtained by diluting the hydrogen peroxide OX-AGUA was evaluated 48% with bidistilled water, with atomized emission flow in the air of 6 ml / m3.

ANALYSIS REPORT FOR ACTIVITIES MICOBACTERICIDE, BACTERICIDE AND FUNGICIDE SOLUTION FOR THE SANISIM PRODUCT.

REFERENCE

Microbiological analysis performed as per estimate issued on 13 July 2017 and accepted by the client on the same day

COMMITTENTE

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MATERIALS AND METHODS

Microorganisms used
Antimicrobial activity tests were performed on the following bacteria:

1. Bacillus subtilis
2. Enterococcus hirae DSM 3320 (corresponding to the ATCC 10541 strain)
3. Escherichia coli DSM 682 (corresponding to the ATCC 10536 strain)
4. Listeria monocytogenes
5. Mycobacterium avium DSM 44157 (corresponding to the ATCC 15769 strain)
6. Mycobacterium terrae DSM 43227 (corresponding to the ATCC 15755 strain)
7. Pseudomonas aeruginosa DSM 939 (corresponding to the ATCC 15442 strain)
8. Salmonella sp. DSM 17058
9. Staphylococcus aureus DSM 799 (corresponding to the ATCC 6538 strain)

And on the following mushrooms:

1. Aspergillus niger DSM 1988 (corresponding to the ATCC 16404 strain)
2. Candida

DSM acronyms indicate that microorganisms were purchased from Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (Braunschweig, Germany); the number following the acronym is the identifier of the strain in the collection. Where not indicated, the strains belong to the collection of the Predictive Microbiology laboratory, University of Foggia. All microorganisms have been revitalized in suitable cultivation conditions, using the laboratory substrates foreseen by the mentioned standards.

Composed analyzed

The preparation to be tested is a ready-to-use solution identified below.
Identification of the formulation: SANISIM SOLUTION
Composition: 6% Hydrogen Peroxide, Silver Complex Salts, F.U.
Lot: 01/17
Expiry date: 03/08/2018

Reference standards

The tests were conducted as indicated in the reference standards:

1. EN 13697: 2005 (Surface bactericidal activity; phase 2, step 2) and EN 14561: 2009 (Surface bactericidal activity; standard phase 2, step 2)
2. EN 14562: 2006 (Surface fungicidal activity; standard phase 2, step 2)
3. EN 14563: 2009 (Mycobactericidal and tuberculocidal activity; surface step 2, phase 2) and EN 14348: 2005 (Mycobactericidal and tubercolicidal activity in suspension; phase 2, step 1)
4. EN 13704: 2005 (Sporicidal activity; phase 2, step 1).

The tests were carried out at 20 ° C in dirty conditions (presence of 3.0 g / l of bovine albumin and 3 ml / l of sheep erythrocytes) (step 2, phase 2) or in the presence of 0.3 g / l of albumin (step 1, phase

Data repeatability and statistical analysis

All tests were performed in duplicate on two different batches; the analyzes were carried out in duplicate on each batch.

The data were expressed as log cfu / ml and as a reduction in cell concentration with respect to the initial time (inoculum) (logR, UNI reference standards); for each test the arithmetic mean values are reported.

TEST RESULTS

The data are expressed as logR (logarithmic reduction) and percentage efficacy. All data refer to phase 2, step 2, except for mushrooms and spores (phase 2, step 1).

Microrganism	Initial concentration (log ufc/ml)	Logarithmic concentration reduction (logR; log ufc/ml)			
		5 min*	10 min	30 min	60 min
Bacillus subtilis (spores)	5,5*10^6	4,55	5,03	>6	>6
Enterococcus hirae	9,2*10^7	5,23	5,45	>7	>7
Escherichia coli	3,2*10^7	4,59	5,03	5,67	5,89
Listeria monocytogenes	8,7*10^6	5,11	5,45	>6	>6
pseudomonas aeruginosa	1,1*10^7	5,04	5,66	6,03	6,07
Salmonella sp.	7,6*10^7	5,13	6,01	>7	>7
Staphylococcus aureus	6,3*10^6	5,23	5,67	>6	>6
Mycobacterium avium	5,1*10^7	5,11	5,23	>7	>7
Mycobacterium terrae	4,0*10^7	5,14	5,44	>7	>7
Aspergillus niger					
Candida albicans	1,2*10^7	2,99	5,21	>7	>7
Bacillus subtilis (spores)	3,4*10^7	3,22	5,31	>7	>7

* Contact time
** Microorganism below the detection threshold

REFERENCE VALUES

Once the validity of the data obtained has been ascertained, a product for the disinfection of medical and surgical instruments complies with the requirements of the reference standard when it determines a **logarithmic reduction R greater than or equal to 5**, under the conditions defined by the European reference standard.

Conclusions

The test has been validated in accordance with the reference prescriptions and the results obtained are to be considered valid.

Based on the results obtained as shown in the previous table, compared to the reference values, it can be concluded that the SANISIM SOLUTION disinfectant product produced by the customer SERVICE DIMENSION demonstrates bactericidal, fungicidal, mycobactericidal and sporicidal effectiveness by surface per Enterococcus hirae, Listeria monocytogenes, pseudomonas aeruginosa, Salmonella spores., Staphylococcus aureus, Mycobacterium avium, Mycobacterium terrae, biocidal activity was observed after 5 min of contact. For Bacillus subtilis (spores), Escherichia coli, Aspergillus niger, and Candida albicans, the biocidal activity was observed after 10 min of contact. In accordance with the requirements of the European standard EN 13697: 2005, EN 14561: 2009, EN 14562: 2009, EN 14563: 2009, EN 14348: 2005 and EN 13704: 2005.

The experimental activity was carried out for some species by the Studio Ambiente s.r.l. certified according to UNI CEI EN ISO 13485: 2012. While the others were carried out by the Tecnolab Laboratory of C. Serino (ACCREDIA accredited pursuant to UNI CEI EN ISO 17025: 2005 for other tests), but which operated in the execution of the same with methods compliant with specific standards and whose results are validated by the Studio Ambiente srl laboratory

A further experimental activity was also performed by the UNIVERSITY OF FOGGIA Department of Agricultural, Food and Environmental Sciences (SAFE)

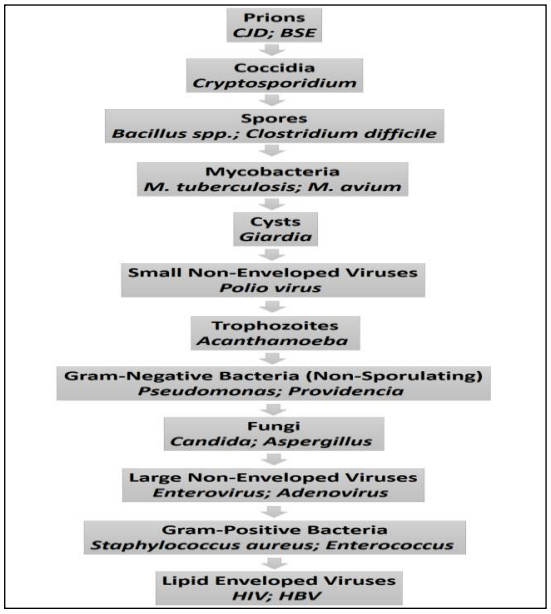
The bacterial load and the amount of silver present in the ambient air before and after sanitization was assessed. The tests were carried out by the Re.Chem.An. s.a.s. in the name of Dr. V.zo Cagnazzo chemist. The tests and tests carried out have been reported in test reports n ° 2340/17, n ° 2341/17 and n ° 2344/17. The efficiency on the ambient air is highlighted with a bacterial load test at 37 ° which also shows the reduction to 0 CFU / m3 after a time of 15 '.

Tests were carried out on the verification of the microbial load also by the accredited EUROFINS BIOLAB laboratory.

As regards the sporicidal and fungicidal activity of SANISIM SOLUTION, the same was considered positive on the basis of the Spaulding scheme (following figure) which classifies the Mushrooms (Candida, Aspergillus, etc) and spores (Bacillus spp, Clostridium difficulty, etc.) as less resistant than Gram negative bacteria to the action of disinfectants and based on previous experimentation.

SPAULDING SCHEME

It follows that any species less sensitive than Gram-negative bacteria to the action of disinfectants is equally susceptible to the chemical action of the disinfectant being tested. Hence, SANISIM SOLUTION, effective against gram-negative and even antibiotic resistant bacteria, is equally, if not more, active towards Mushrooms, Enterovirus, Adenovirus, HIV, HBV and the like..



All reports of tests carried out to confirm SANISIM SOLUTION's activity are listed in Annex 7 "Effectiveness tests".

A Good Company

http://www.e2s3.eu/E2S3-SaniSim/index.php

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