List of standards for validation of chemical surface disinfection and
Expert Statements about the Diosol®-System
Only relevant Standard, updated Mai 2016, please note additional information!

Standard/date of publication M/JJJJ	Title	Short summary of content	Diosol®-Expert Statement Results
European Standards - Chemical disinfectants and antiseptics. CEN/TC 216			
EN 1040 3/2006	Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics. Test method and requirements (phase 1)	Suspension-based study used as a presumptive test to evaluate basic bactericidal activity against Staphylococcus aureus ATCC 5638 and Pseudomonas aeruginosa ATCC 15422	Target Reduction factor (RF) of 5 was reached at concentration of 6 % and exposition time of 30 min and 2 %, exposition time of 60 min.
EN 1276 1/2010	Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas- Test method and requirements (phase 2, step 1)	This test method evaluates how effectively the product to cause a reduction in the number of viable bacterial cells of the relevant test microorganismsusing clean conditions (0,03% bovine serum albumine (BSA) and dirty conditions (0,3 % BSA), RF 5* required	Clean conditions: concentration of 12 %, exposition time 60 min Here the formulated product was testet
EN 1275 3/2006	Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics. Test method and requirements (phase 1)	Suspension-based study used as a presumptive test to evaluate basic fungicidal activity using Candida albicans ATCC 10231 und Aspergillus niger (brasiliensis) ATCC 16404	NO NEED
EN 1650 8/2013	Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (Phase 2, step 1)	Requirements like EN 1276, RF* 4 should be reached	Clean Conditions: Conzentration 5 %, Expostion time 60 min Dirty Conditions: Conzentration 6 %, Exposure time 60 min (RF* 7!)
EN ISO 11138-1:2006-09	Sterilization of health care products, Biological indicators -- Part 1: General requirements	Geobacillus stearothermophilus used as Indicator	No need, but indicators are used for validation (see RKI-List)
EN 12353 4/2013	Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity	Advice for laboratories testing chemical disinfectants	NO NEED

*) RF = Reduction factor in $\log_{10}$-Steps. A test product has to reduce within the exposition time from 100.000 colony forming units (cfu) to 1 cfu. A RF of 4 means a reduction from 10.000 to 1 cfu and RF 3 represent a reduction von 1.000 auf 1 cfu.

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EN 14347 8/2005	Basic sporicidal activity. Test method and requirements (phase 1, step 1)	Testing a principal effect on spores of Bacillus subtilis ATCC 6633 and Bacillus cereus ATCC 12826	Conzentration: 25,8% Exposure time: 5 bis 6 min pH: around 7 temperature: 24°C Clean conditions Applikation: Spraying, Rinsing, Diving
EN 13 704 5/2002	Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. Test method and requirements (phase 2, step 1)	Requirements similar to EN 1276, but RF* 3	Sporicidal effect was demonstrated within RKI-Validation (see downside)
EN 13 697 6/2015	Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. Test method and requirements without mechanical action (phase 2, step 2)	Carrier-based study formally used to evaluate bactericidal and fungicidal activity on non-porous surfaces using the test organisms. *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Enterococcus hirae*, *Escherichia coli*, *Candida albicans*, *Aspergillus brasiliensis*	No Need
EN 14348 9/2005	Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements (phase 2, step 1)	Suspension-based study formally used to evaluate mycobactericidal activity of products that are used in the medical area, test organisms are Mycobacterium avium, Mycobacterium terrae, Clean condition (0,03% BSA) and dirty conditions (0,3 % BSA), RF 5* required	Clean condition, Suspensiontest: 6 % exposition of 60 min Fogging: 10 % exposition time 90 min
EN 14476 12/2015	Quantitative suspension test for the evaluation of virucidal activity in the medical area. Test method and requirements (Phase 2/Step 1)	Suspension-based study used as a presumptive test to evaluate virucidal activity. Adenovirus, Poliovirus Bovine, Parvovirus, and additional pathogens. RF* 4 is required	EN 14476:2007 Noroviruses (MNV)Clean conditions (0,03 % BSA) viruzide action against Noroviruses 3 % Exposure time 60 min

Standards not used in whole Europe			
Standard/date of publication M/JJJJ	**Title**	**Short summary of content**	**Diosol®-Expert Statement Results**
NF T 72-281 11/2014	Procédés de désinfection des surfaces par voie aérienne - Détermination de l'activité bactéricide, fongicide, levuricide, mycobactéricide, tuberculocide sporicide et virucide incluant les bactériophages	Fogging surface dinfectans, bactericidal action against: Pseudomonas aeruginosa (CIP 103-467), Staphylococcus aureus (CIP 4.83), Enterococcus hirae (CIP 5855), Escherichia coli (CIP 54127) Sporizide action: Bacillus subtilis (CIP 52 62) Fungizide action: Candida albicans (IP 4872), Aspergillus niger (IP 1431-83) Levurozidie: Candida albicans (IP4872).	Virucidic action: Tested with Influenza A H1N1, human Rotavirus, murine Norovirus, Adenovirus Typ 5, Poliovirus Typ 1; Clean conditions (0,03 % BSA)

Validation standard by Robert-Koch-Institute of Germany			
Point	**Title**	**Content**	**Diosol®-Expert Statement**
3.3.2	Wasserstoffperoxid-Verfahren Hydrogen peroxide treatment of surfaces by fogging	Temperature, % rel. humidity concentration of hydrogene peroxide concentration in room, Process data of generators, condition optimizing (e. g. drying), One have to check and document: Points in room difficult to reach, spread of gas Placement of generator and additional equipment like ventilators Inactivation of spores of Geobacillus stearothermophilus (see DIN EN ISO 11138) on relevant surfaces (Filtration paper, metal), maybe in body fluids like blood. Further points are Material compatibility Reproduction of process results Residual concentration of H_2O_2 after process (<1 ppm)	Validierung unter verschiedenen Bedingungen bestanden.

Disinfection in veterinary section			
Standard/date of publication M/JJJJ	**Title**	**Short summary of content**	**Diosol®-Expert Statement Results**
EN 1656 11/2010	Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area. Test method and requirements (phase 2, step 1)	Suspension test with different microorganisms in BSA	Fulfilled
EN 1657 3/2006	Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area. Test method and requirements (phase 2, step 1)	Fungi (Yeasts and Molds) will be suspended with BSA and test product	fulfilled
EN 14 204 2/2013	Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants and antiseptics used in the veterinary area. Test method and requirements (phase 2, step 1)	mycobacteria (Non Tuberculosis Complex) will be suspended with BSA and test product	fulfilled
EN 14 349 2/2013	Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on non-porous surfaces without mechanical action. Test method and requirements (phase 2, step 2)	Clean conditions are 0,3 % BSA, dirty conditions are 1 % milk	no data

Practical Test by Court Advisors Office Institut Schwarzkopf GbR in collaboration with Labor LS AG, Bad Bocklet
The application of 1 % BSA and erythrocytes (three times of dirty conditions in the usual standards) on non-pourous surfaces showed a well visible contamination, no mechanical cleaning was done. The Diosol Generator was placed according to the instructions of the manufacturer. Diosol fog volumina were chosen correlating to the room volume. Test surfaces were placed even in places different to reach by fog. Test bacterium was Enterococus faecium ATCC 6057 in a concentration of 10^6 cfu per test surface. Within the fog area a germ reduction of RF 5 (100.000 cfu to 1 cfu) of test germ. The lowest RF found was RF 2 in surfaces in a far position outside the fog area. This is the analogon of a well done cleaning process.

Information:
The development and further testing of a chemical surface disinfectant is done in different phases, some of them are further divided in so called steps.

Phase	Step	Testinhalt
-	-	Toxicity tests, classification of hazardous substances if needed
1	-	Estimation of antimicrobial action on Staphylococcus aureus ATCC 5638 and Pseudomonas aeruginosa ATCC 15422 (Standard EN 1040), Candida albicans ATCC 10231 and Aspergillus niger (brasiliensis) ATCC 16404 (Standard EN 1275), Bacillus subtilis ATCC 6633 and Bacillus cereus ATCC 12826 Standard EN 14347)
2	1	Suspension Test (Microorganisms are “swimming” in disinfectant, “clean” and “dirty” conditions
	2	Practical test using standardized test surfaces, Institutions of foodstuff processing, industrie and official institutions
-	-	Four fields test for wipes