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Tests Performed on Guardian Technology disinfection

EN Test	Description of Test	Test organism
EN 1276	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (Phase 2, step 1).	<i>P.aeruginosa</i> , <i>S.typhimurium</i> , <i>S.aureus</i> , <i>E.hirae</i> , <i>E.coli</i> , <i>MRSA</i> , <i>V. cholerae</i> , <i>A. baumannii</i>
EN 13727	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area - Test method and requirements (phase 2, step 1)	<i>P.aeruginosa</i> , <i>S.aureus</i> , <i>E.hirae</i>
EN 13697	Chemical disinfectants and antiseptics. 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)	<i>P.aeruginosa</i> , <i>S.typhimurium</i> , <i>S.aureus</i> , <i>E.hirae</i> , <i>E.coli</i> , <i>A.niger</i> , <i>C.albicans</i>
EN 14349	Chemical Disinfectants And Antiseptics - 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)	<i>P.aeruginosa</i> , <i>P.vulgaris</i> , <i>S.aureus</i> , <i>E. hirea</i>
EN 13704	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).	<i>B.subtilis</i> spores, <i>C.difficile</i> spores
EN 1650	Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas. Test method and requirements (phase 2, step 1)	<i>A.niger</i> , <i>C.albicans</i>
EN 1657	Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in veterinary field. Test method and requirements (phase 2/step 1)	<i>A.niger</i> , <i>C.albicans</i>
EN 13624	Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area. Test method and requirements (phase 2, step 1)	<i>A.niger</i> , <i>C.albicans</i>
EN 14563	Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2)	<i>M. terrae</i> <i>M. avium</i>
DIN EN 14476	Chemical disinfectants and antiseptics - Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2, step 1); German version EN 14476:2005 +A1:2006 (Version: February 2007).	<i>Vaccinia Virus</i> and <i>Bovine Viral</i> <i>Diarrhoea Virus</i> - <i>BVDV</i>



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EN 12791	Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirement (phase 2/step 2)	Bacterial flora on 20 different persons
EN 1500	Chemical disinfectants and antiseptics. Hygienic handrub. Test method and requirements (phase 2/step 2) (fas 2, steg 2)	<i>E.coli</i>

Virus Tests:

The following virus tests have been performed according to the American Test Standard ASTM 1052-11

Analytical report Vaccinia virus

Analytical report Human Herpesvirus Type 1

Analytical report Human Rotavirus (WA strain)

Analytical report Feline calicivirus (as Norovirus surrogate)

Analytical report Bovine viral diarrhea virus (HCV Surrogate)

Analytical report Pseudorabies Virus (HBV surrogate)

Analytical report Influenza A virus (subtype H3N2)

Other Tests:

The following tests have been conducted to verify specific questions regarding the performance of Guardian Technology.

Analytical report skin irritation, reconstructed human epidermis (RHE)

Final report Guardian Technology, Skin irritation

Report on antibacterial evaluation of frozen Guardian Technology after thawing – Aerosol test

Long lasting effect of Guardian Technology “aerosol test”

Long lasting effect of rinsed sample of Guardian Technology “aerosol test”

Report on antibacterial evaluation (Guardian/Cationic binder) “Aerosol test”

Determination of the antibacterial effect of Guardian Technology 12 hours after treatment

Microbiological Analysis report – test for antimicrobial activity and efficacy on plastic, metals or ceramic surfaces using JIS Z 2801: 2000 test method

Guardian Technology Test Report, Freezing and Thawing (Aerosol test)

Report shelf life of Guardian Technology



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Conclusion:

In conclusion the tests show that Guardian Technology is:

- Well tested on a broad range of microorganisms, viruses and spores according to established EN and ASTM standard methods for disinfection agents according to test reports listed in the Technical File, product verification and validation. The EN standards are selected from “Vårdhandboken” and EN 14885:2006 that constitutes the state-of-the-art on methods for disinfection agents.
- Proven to pass, by far, the criteria for disinfection on all EN tests performed under the most difficult type of test condition (dirty conditions).
- Tested for efficacy on an extended set of microorganisms than originally stated in the EN test set-up (*V. cholerae*, *C. difficile* and MRSA test reports)
- Capable of disinfecting and rendering a long term effect on general medical device type of surface materials (PE and PVC plastics, glass, tile, stainless steel, linoleum, wood or porous materials and textiles) giving the dry, treated surfaces an extra level of safety in between disinfection actions or routines. The effect has also been proven for rinsed samples, hence the long-term effect is binding to the surface treated with Guardian Technology.
- Safe for the user, proven by external skin irritations test reports.
- A product with the unique feature of being suitable as a product both for inanimate surfaces and hands.
- Safe to use on the intended medical device surfaces according to literature support and tests on typical medical device materials.