



Die Nationale Akkreditierungsstelle / *The National Accreditation Body*

## AKKREDITIERUNG AUSTRIA

bestätigt die Akkreditierung der Rechtsperson / *confirms the accreditation of*

### HygCen Austria GmbH

Werksgelände 28, A-5500 Bischofshofen

Identifikationsnummer / *ID-number*: **0196**

als / *as*

**Prüfstelle / *Testing Laboratory***

gemäß / *according to*

**EN ISO/IEC 17025:2005**

Datum der Erstakkreditierung / *Initial date of accreditation*: **27.12.2001**

Standort/Organisationseinheit / *site/unit*:


**HygCen Austria GmbH, Werksgelände 28, A-5500 Bischofshofen**

Informationen zum Akkreditierungsumfang und zu Akkreditierung Austria / *Information about the accreditation scope and Akkreditierung Austria* <http://www.bmdw.gv.at/akkreditierung>

Die Akkreditierung wurde mittels Bescheid erteilt und damit bestätigt, dass die Konformitätsbewertungsstelle die angeführten Anforderungen erfüllt. Diese Bestätigung darf nur unverändert weiterverbreitet werden.

*The accreditation was granted by a decree which confirms, that the Conformity Assessment Body fulfills the given requirements. This confirmation of accreditation may not be reproduced other than in full.*

19.06.2018  
Datum / *Date*

  
Dipl.-Ing. Dr. Norman Brunner  
Leiter Akkreditierung Austria / *Head, Akkreditierung Austria*



## Testing Laboratory

legal entity **HygCen Austria GmbH**  
Werksgelände 28, 5500 Bischofshofen  
web [www.hygcen.at](http://www.hygcen.at)

ident No **0196**  
site **HygCen Austria GmbH**  
Werksgelände 28, 5500 Bischofshofen

initial date of accreditation **2001-12-27**  
level 3 accreditation standard **EN ISO/IEC 17025:2005**  
according to EA-1/06

According to § 7 AkkG 2012, the harmonized Level 3 accreditation standard on which the accreditation is based and as well as the applicable instruction documents/guides or obligatory declared normative documents from EA - European co-operation for Accreditation, the ILAC - International Laboratory Accreditation Cooperation and the Accreditation Austria in the valid version must be observed and complied with.

Accreditation is additionally granted in accordance with the following

other requirements EA-3/01:2012  
ILAC-P9:2014  
ILAC-P10:2013

**Scope of Accreditation of Testing Laboratory (EN ISO/IEC 17025:2005)  
HygCen Austria GmbH / (ID No 0196)**

valid from: 2020-03-31

document number (issue)	<sup>1)</sup>	title of the standard or SOP	<sup>2)</sup>	carried out tests / <sup>3)</sup> types of tests / techniques / methods /	materials / products	components / parameters / characteristics	remarks
16-009 (2014-05)	S	Testing of the cleaning efficacy of washer disinfectors for thermostable & thermolabile medical devices in accordance with the guideline of ÖGSV respectively DGKH, DGSV and AKI		Photometry	thermolabile medical devices	Protein residues after cleaning	The cleaning performance is checked with the aid of test specimens which are soiled; the evaluation according to the modified OPA-method
16-010 (2014-11)	S	Testing of the cleaning efficacy of washer disinfectors for thermolabile endoscopes in accordance with the guideline of ÖGSV		Photometry	thermolabile endoscopes	Residual proteins after cleaning	The cleaning performance is checked with the help of endoscopic Dummies; the evaluation is done optically
17-008 (2012-09)	S	Quantitative determination of free NH <sub>2</sub> groups of blood-proteins by the modified OPA method		Photometry	aqueous liquids	NH <sub>2</sub> -Gruppen (Proteins)	The determination of the residual proteins of soiling by the modified OPA-method is carried out photometrically and serves to demonstrate the cleaning performance.
ASTM F 1670/F 1670Ma (2017-01)	N	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood		Penetration procedure with synthetic blood	Fabrics of Protective Clothing	Resistance to penetration	
ASTM F 1671/F 1671M (2013-01)	N	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System		Phi-X174-Bacteriophage-Intrusion procedure	Fabrics for Protective Clothing	Pathogenic germs	
DIN 38409-9 (1980-07)	N	German standard methods for the examination of water, waste water and sludge; general measures of effects and substances (group H), determination of the settleable matter by volume in water and waste water (H9)		Volumetric process	Drinking water, ground and surface water, process water, waste water	removable substances	

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EN 1040 (2005-12)	N	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics – Test method and requirements (phase 1)		quantitative suspension test	chemical disinfectants and antiseptics	bactericidal activity	
EN 1275 (2005-12)	N	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of basic fungicidal or basic yeastcidal activity of chemical disinfectants and antiseptics – Test method and requirements (phase 1)		quantitative suspension test	chemical disinfectants and antiseptics	fungicidal or yeastcidal activity	
EN 1276 (2019-08)	N	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 – Test method and requirements (phase 2, step 1)		quantitative suspension test	chemical disinfectants and antiseptics	bactericidal activity	
EN 12791+A1 (2017-11)	N	Chemical disinfectants and antiseptics – Surgical hand disinfection – Test method and requirements (phase 2, step 2)		quantitative suspension test	Surgical hand disinfection	Mode of action	
EN 13098 (2019-09)	N	Workplace exposure - Measurement of airborne microorganisms and microbial compounds		pour plate method, colony counting method	Workplace exposure	airborne microorganisms and microbial compounds	

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EN 13623 (2010-09)	N	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity against Legionella of chemical disinfectants for aqueous systems – Test method and requirements (phase 2, step 1)		quantitative suspension test	chemical disinfectants for aqueous systems	bactericidal activity against Legionella	
EN 13697+A1 (2019-07)	S	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)		quantitative non-porous surface test	chemical disinfectants used in food, industrial, domestic and institutional areas	bactericidal and/or fungicidal activity	
EN 13704 (2018-07)	N	Chemical disinfectants – 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)		quantitative suspension test	chemical disinfectants used in food, industrial, domestic and institutional areas	sporicidal activity	
EN 13727+A2 (2015-10)	N	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1)		quantitative suspension test	chemical disinfectants and antiseptics in the medical area	bactericidal activity	

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EN 14126 (2003-09)	N	Protective clothing - Performance requirements and test methods for protective clothing against infective agents		differential pressure method, penetration method	Protective Clothing against infective agents	Breathability, bacterial filter performance (BFP)	
EN 14204 (2012-11)	N	Chemical disinfectants and antiseptics – 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)		quantitative suspension test	chemical disinfectants and antiseptics used in the veterinary area	mycobactericidal activity	
EN 14347 (2005-03)	N	Chemical disinfectants and antiseptics – Basic sporicidal activity – Test method and requirements (phase 1)		basic test	chemical disinfectants and antiseptics	sporicidal activity	
EN 14348 (2005-01)	N	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants – Test method and requirements (phase 2, step 1)		quantitative suspension test	chemical disinfectants and antiseptics in the medical area, instrument disinfectants	mycobactericidal activity	
EN 14349 (2012-11)	N	Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action – Test method and requirements (phase 2, step 2)		quantitative surface test	chemical disinfectants and antiseptics used in the veterinary area	bactericidal activity on non-porous surfaces without mechanical action	

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EN 14561 (2006-05)	N	Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2)		quantitative carrier test	chemical disinfectants and antiseptics for instruments in the medical area	bactericidal activity	
EN 14562 (2006-05)	N	Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2)		quantitative carrier test	chemical disinfectants and antiseptics for instruments in the medical area	fungicidal or yeasticidal activity	
EN 14563 (2008-11)	N	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)		quantitative carrier test	chemical disinfectants and antiseptics for instruments in the medical area	mycobactericidal activity	
EN 14683+AC (2019-08)	N	Medical face masks - Requirements and test methods		test method	medical face masks	Permeability	- Appendix B: Procedure for the vitro determination of bacterial filter performance (BFP) - Appendix C: Procedure for determining breathability (pressure difference)
EN 1499 (2013-04)	N	Chemical disinfectants and antiseptics – Hygienic handwash – Test method and requirements (phase 2 / step 2)		hygienic handwash	chemical disinfectants and antiseptics	Determination of effectiveness	

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EN 1500 (2013-04)	N	Chemical disinfectants and antiseptics - Hygienic handrub – Test method and requirements (phase 2 / step 2)		Hygienic handrub	chemical disinfectants and antiseptics	Determination of effectiveness	
EN 1650 (2019-08)	N	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)		quantitative suspension test	chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas	fungicidal or yeasticidal activity	
EN 1656 (2019-09)	S	Chemical disinfectants and antiseptics - 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)		quantitative suspension test	chemical disinfectants and antiseptics used in the veterinary area	bactericidal activity	
EN 1657 (2016-04)	N	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)		quantitative suspension test	chemical disinfectants and antiseptics used in the veterinary area	fungicidal or yeasticidal activity	



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EN 16615 (2015-04)	N	Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) - Test method and requirements (phase 2, step 2)		Quantitative test method (4- field test)	chemical disinfectants and antiseptics in the medical area	bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes	
EN 16616 (2015-08)	N	Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2)		Chemical-thermal textile disinfection	chemical disinfectants and antiseptics	Efficacy of disinfectants, antiseptics	
EN 27888 (1993-09)	N	Water quality; determination of electrical conductivity (ISO 7888:1985)		Conductometry	Drinking water, ground and surface water, process water, waste	electric conductivity	
EN 29073-3 (1992-06)	N	Textiles; test method for nonwovens; part 3: determination of tensile strength and elongation		Tensile tests	Textiles, nonwovens	Maximum tensile force, maximum tensile elongation	
EN 455-1 (2000-10)	N	Medical gloves for single use - Part 1: Requirements and testing for freedom from holes		Leak test	Medical gloves for single use	Tightness	
EN 455-2 (2015-04)	N	Medical gloves for single use - Part 2: Requirements and testing for physical properties		Physical methods	Medical gloves for single use	Physical Properties	
EN ISO 10523 (2012-02)	N	Water quality - Determination of pH (ISO 10523:2008)		Electrochemical processes	Drinking water, ground and surface water, process water, waste	pH value	
EN ISO 11731 (2017-06)	N	Water quality – Counting of Legionella		Membrane filtration	Drinking water, ground and surface water, process water, waste	Legionella	

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EN ISO 11737-1 (2018-01)	N	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)		Pour plate method, colony counting method	Health care products	Microorganisms, colony forming units (cfu)	
EN ISO 11737-2 (2019-04)	N	Sterilization of medical devices – Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of the sterilization process (ISO/DIS 11737-2:2018)		Pour plate method, colony counting method	medical devices	Sterility test	
EN ISO 13934-1 (2013-04)	N	Textiles - Tensile properties of fabrics - Part 1: Determination of maximum force and elongation at maximum force using the strip method (ISO 13934-1:2013)		Strip-Tensile test	textile fabrics	Maximum traction, Maximum tensile strength expansion	
EN ISO 13934-2 (2014-02)	N	Textiles - Tensile properties of fabrics - Part 2: Determination of maximum force using the grab method (ISO 13934- 2:2014)		Grab-Tensile test	textile fabrics	Maximum traction	
EN ISO 13937-2 (2000-04)	N	Textiles - Tear properties of fabrics - Part 2: Determination of tear force of trouser- shaped test specimens (single tear method) (ISO 13937-2:2000)		Thigh tear attempt	textile fabrics	Tear strength	
EN ISO 13938-1 (2019-12)	N	Textiles - Bursting properties of fabrics - Part 1: Hydraulic method for determination of bursting strength and bursting distension (ISO 13938-1:2019)		Hydraulic process	textile fabrics	Bursting pressure and bursting arch	
EN ISO 14644-1 (2015-12)	N	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)		Sampling method according to Chapter A5	Cleanrooms	Sampling - Particle	

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EN ISO 16266 (2008-02)	N	Water quality – Detection and enumeration of <i>Pseudomonas aeruginosa</i> by membrane filtration (ISO 16266:2006)		Membrane filtration	Drinking water, ground and surface water, process water, waste water	<i>Pseudomonas aeruginosa</i>	
EN ISO 18593 (2018-07)	N	Microbiology of the food chain - Horizontal methods for surface sampling (ISO 18593:2018)		- Contact printing - Swab method	Surface	Sampling	
EN ISO 19458 (2006-08)	N	Water quality – Sampling for microbiological analysis (ISO 19458:2006)		- Scooping samples - Tap withdrawals - Direct withdrawals	Drinking water, ground and surface water, process water	Sampling	
EN ISO 20743 (2013-07)	N	Textiles - Determination of the antibacterial activity of textile products (ISO 20743:2013)		microbiological process	Textiles	antibacterial activity	
EN ISO 22610 (2006-07)	N	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Test method to determine the resistance to wet bacterial penetration (ISO 22610:2006)		Germination procedure	Surgical drapes, gowns and clean air suits	resistance to wet bacterial penetration	
EN ISO 22612 (2005-03)	N	Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration (ISO 22612:2005)		Penetration process when dry	Textiles als Schutz gegen infektiöse Agenzien	resistance to microbial penetration	
EN ISO 6222 (1999-05)	N	Water quality - Enumeration of culturable micro-organisms - Colony count by inoculation in a nutrient agar culture medium (ISO 6222:1999)		pour plate method, colony counting method	Drinking water, ground and surface water, process water, waste water	Colony forming units (cfu at 22°C and 36°C)	

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EN ISO 6330 (2012-04)	N	Textiles - Domestic washing and drying procedures for textile testing (ISO 6330:2012)		Non-commercial washing and drying processes - restricted to processes A, B, C, D, F	Textiles	Test with textiles restricted to processes A, B, C, D, F	
EN ISO 7899-2 (2000-04)	N	Water quality – Detection and enumeration of intestinal enterococci - Part 2: Membrane filtration method (ISO 7899-2:2000)		Membrane filtration	Drinking water, ground and surface water, process water, waste water	intestinal enterococci	
EN ISO 811 (2018-05)	N	Textiles - Determination of resistance to water penetration - Hydrostatic pressure test (ISO 811:2018)		Hydrostatic pressure test	Textiles	resistance to water penetration	
EN ISO 9073-10 (2004-12)	N	Textiles - Test methods for nonwovens - Part 10: Lint and other particles generation in the dry state (ISO 9073-10:2003)		test method	Textiles, nonwovens	Fiber fragments, other particles	
EN ISO 9073-4 (1997-07)	N	Textiles — Test methods for nonwovens — Part 4: Determination of tear resistance (ISO 9073-4:1997)		Tensile strength test	Textiles	Strength	
EN ISO 9073-6 (2003-03)	N	Textiles - Test methods for nonwovens - Part 6: Absorption (ISO 9073-6:2000)		Physical process	Textiles, nonwovens	Absorption	
EN ISO 9308-1/A1 (2017-01)	S	Water quality - Enumeration of Escherichia coli and coliform bacteria - Part 1: Membrane filtration method for waters with low bacterial background flora (ISO 9308-1:2014/Amd 1:2016)		Membrane filtration	Drinking water, ground and surface water, process water, waste water	Escherichia coli, coliform bacteria	
ISO 16000-1 (2004-07)	N	Indoor air - Part 1: General aspects of sampling strategy		Sampling method	Indoor air	Sampling	

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ISO 16603 (2004-04)	N	Clothing for protection against contact with blood and body fluids - Determination of the resistance of protective clothing materials to penetration by blood and body fluids - Test method using synthetic blood		test method with synthetic blood	Protective Clothing	Resistance against penetration by blood and body fluids	
ISO 16604 (2004-04)	N	Clothing for protection against contact with blood and body fluids - Determination of resistance of protective clothing materials to penetration by blood-borne pathogens - Test method using Phi-X 174 bacteriophage		test method with bacteria Phi-X174	Protective Clothing	Resistance against penetration by blood	
ISO 22609 (2004-12)	N	Clothing for protection against infectious agents - Medical face masks - Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)		test method with synthetic blood	medical face masks	Resistance against penetration by infectious agents	
ISO 5667-5 (2006-04)	N	Water quality — Sampling - Part 5: Guidance on sampling of drinking water from treatment works and piped distribution systems		- Scooping samples - Tap withdrawals - Direct withdrawals	Drinking water	Sampling	
ISO/TS 15883-5 (2005-11)	N	Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy		Test protection procedures	Washer-disinfectors	cleaning efficacy	
JIS L 1902 (2008-10)	N	Testing for antibacterial activity and efficacy on textile products		test method according to Chapter 3	Antibacterial textiles	antibacterial activity and efficacy	
JIS Z 2801/Amendment1 (2015-07)	N	Antimicrobial products-Test for antimicrobial activity and efficacy		test method according to Chapter 5	Antimicrobial products	antimicrobial activity and efficacy	

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OENORM M 6616 (1994-03)	N	Water analysis - Determination of temperature		Temperature measurement	Drinking water, ground and surface water, process water, waste	Temperature	
Ph.Eur. 2.6.1 (2012-01)	N	Testing for microbial contamination in sterile products: enumeration of total, viable, aerobe and anaerobe microorganisms		pour plate method, colony counting method	Medicines	Colony forming units of total, viable, aerobe and anaerobe microorganisms	
Ph.Eur. 2.6.12 (2012-01)	N	Microbiological Examination of non-steril products: microbial enumeration tests		Sedimentation process	Indoor air	Sampling	
prEN 13624 (2019-08)	N	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area – Test method and requirements (phase 2, step 1)		quantitative suspension test	chemical disinfectants and antiseptics in the medical area	fungicidal or yeasticidal activity	
prEN 17272 (2018-08)	N	Chemical Disinfectants and Antiseptics - Quantitative Carrier test for Airborne Room Disinfection by Automated Processes - Determination of Bactericidal, Fungicidal, Yeasticidal, Sporicidal, Tuberculocidal, Mycobactericidal, Virucidal and Phagocidal Activities in the Medical Area, Veterinary Area and Food, Industrial, Domestic and Institutional Areas - Test Methods and Requirements (Phase 2, Step 2)		Quantitative Germ carrier test	chemical disinfectants and antiseptics in the medical area, Veterinary Area and Food, Industrial, Domestic and Institutional Areas	Determination of Bactericidal, Fungicidal, Yeasticidal, Sporicidal, Tuberculocidal, Mycobactericidal, Virucidal and Phagocidal Activities	
VAH method 14 (2019-03)	N	Requirements and methods to the VAH-certified chemical disinfection methods: surface disinfection without mechanics – practical test (method 14)		Surface disinfection (practical test)	Chemical disinfection methods	Effectiveness check	

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VAH method 15 (2019-03)	N	Requirements and methods to the VAH-certified chemical disinfection methods: chemical/ chemo- thermal disinfection of instruments - practical quantitative germ carrier test (method 15)		practical quantitative Germ carrier test	chemical disinfection methods: chemical/ chemo- thermal disinfection of instruments	Effectiveness check	
VAH method 17 (2019-03)	N	Requirements and methods to the VAH-certified chemical disinfection methods: chemo- thermal laundry disinfection – single bath method (practical test) (method 17)		One bath procedure (practical Test)	chemo- thermal laundry disinfection	Effectiveness check	
VAH method 7 (2019-03)	N	Requirements and methods to the VAH-certified chemical disinfection methods: determination of the bacteriostatic and levurostatic effectiveness as well as suitable neutralizer (method 7)		test method	Chemical disinfection methods	determination of the bacteriostatic and levurostatic effectiveness	
VAH method 8 (2019-03)	N	Requirements and methods to the VAH-certified chemical disinfection methods: determination of the bactericidal and yeasticidal effectiveness in a qualitative suspension test (method 8)		qualitative suspension test	Chemical disinfection methods	determination of the bactericidal and yeasticidal effectiveness	
VAH method 9 (2019-03)	N	Requirements and methods to the VAH-certified chemical disinfection methods: determination of the bactericidal, yeasticidal, fungicidal, tuberculocidal or mycobactericidal effectiveness in a quantitative suspension test (method 9)		quantitative suspension test	Chemical disinfection methods	determination of the bactericidal, yeasticidal, fungicidal, tuberculocidal or mycobactericidal effectiveness	

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- 1) Types of tests : standard (N) or SOP (S); Any amendments of standards apply as with accredited, provided that there is no new conformity assessment procedures are defined.  
Austrian laws and regulations as well as EU regulations are accredited in the applicable version, unless otherwise indicated.*
- 2) Conformity assessment procedures can - if selected - also be carried out on site.*
- 3) Techniques / methods / equipment are mentioned if applicable and only if there is an influence on the measurement result.*