



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

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 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.

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

valid from: 2018-05-16

No.	document number of the standard or SOP ¹⁾	issue	title of the standard or SOP	remarks	PvO 2)
1	02-030	2008-05	Testing on the cleaning efficacy of chemo-thermal laundry disinfection procedures in laundries		<input type="checkbox"/>
2	11-001	2017-04	Hygienic examination of surrounding areas in reprocessing facilities for medical devices and similar		<input type="checkbox"/>
3	16-009	2014-05	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		<input type="checkbox"/>
4	16-010	2014-11	Testing of the cleaning efficacy of washer disinfectors for thermolabile endoscopes in accordance with the guideline of ÖGSV		<input type="checkbox"/>
5	17-008	2012-09	Quantitative determination of free NH ₂ groups of blood-proteins by the modified OPA method		<input type="checkbox"/>
6	DGHM Chapter 4	2001-09	Standard DGHM methods of testing chemical disinfectants - Chapter 4: Testing of the disinfecting efficacy of chemo-thermal laundry disinfection procedures in laundries (DGHM)		<input type="checkbox"/>
7	DIN 1946-4	2008-12	Ventilation and air conditioning – Part 4: Ventilation in buildings and rooms of health care		<input type="checkbox"/>
8	DIN 38409-9	1980-07	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 (H 9)		<input type="checkbox"/>

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9	DIN 38411-8	1982-05	German standard methods for the analysis of water, waste water and sludge; Microbiological methods (group K); Detection of <i>Pseudomonas aeruginosa</i> (K 8)		<input type="checkbox"/>
10	EN 1040	2005-12	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)		<input type="checkbox"/>
11	EN 1275	2005-12	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics – Test method and requirements (phase 1)		<input type="checkbox"/>
12	EN 1276	2009-10	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)		<input type="checkbox"/>
13	EN 12791+A1	2017-11	Chemical disinfectants and antiseptics – Surgical hand disinfection – Test method and requirements (phase 2, step 2)		<input type="checkbox"/>
14	EN 13098	2000-09	Workplace atmosphere - Guidelines for measurement of airborne microorganisms and endotoxin		<input type="checkbox"/>

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15	EN 13623	2010-09	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)		<input type="checkbox"/>
16	EN 13624	2013-09	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)		<input type="checkbox"/>
17	EN 13697	2015-04	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)		<input type="checkbox"/>
18	EN 13704	2002-02	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)		<input type="checkbox"/>

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19	EN 13727+A2	2015-10	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)		<input type="checkbox"/>
20	EN 14204	2012-11	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)		<input type="checkbox"/>
21	EN 14347	2005-03	Chemical disinfectants and antiseptics – Basic sporicidal activity – Test method and requirements (phase 1)		<input type="checkbox"/>
22	EN 14348	2005-01	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)		<input type="checkbox"/>
23	EN 14349	2012-11	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)		<input type="checkbox"/>

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No.	document number ¹⁾ of the standard or SOP	issue	title of the standard or SOP	remarks	PvO ²⁾
24	EN 14561	2006-05	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)		<input type="checkbox"/>
25	EN 14562	2006-05	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)		<input type="checkbox"/>
26	EN 14563	2008-11	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)		<input type="checkbox"/>
27	EN 1499	2013-04	Chemical disinfectants and antiseptics – Hygienic handwash – Test method and requirements (phase 2 / step 2)		<input type="checkbox"/>
28	EN 1500	2013-04	Chemical disinfectants and antiseptics - Hygienic handrub – Test method and requirements (phase 2 / step 2)		<input type="checkbox"/>
29	EN 1650+A1	2013-05	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)		<input type="checkbox"/>

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30	EN 1657	2016-04	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)		<input type="checkbox"/>
31	EN 16615	2015-04	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)		<input type="checkbox"/>
32	EN 16616	2015-08	Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2)		<input type="checkbox"/>
33	EN 26461-2	1993-01	Water quality – Detection and enumeration of the spores of sulfite-reducing anaerobes (clostridia); part 2: method by membrane filtration (ISO 6461-2:1986)	not for the analysis of drinking water according to TW-VO	<input type="checkbox"/>
34	EN 27888	1993-09	Water quality; determination of electrical conductivity (ISO 7888:1985)		<input type="checkbox"/>
35	EN ISO 10523	2012-02	Water quality - Determination of pH (ISO 10523:2008)		<input type="checkbox"/>
36	EN ISO 11737-1	2018-01	Sterilization of medical devices – Microbiological methods - Part 1: Determination of a population of micro-organisms on products (ISO 11737-1:2018)		<input type="checkbox"/>

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37	EN ISO 11737-2	2009-11	Sterilization of medical devices – Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of the sterilization process (ISO 11737-2:2009)		<input type="checkbox"/>
38	EN ISO 16266	2008-02	Water quality – Detection and enumeration of Pseudomonas aeruginosa by membrane filtration (ISO 16266:2006)		<input type="checkbox"/>
39	EN ISO 19458	2006-08	Water quality – Sampling for microbiological analysis (ISO 19458:2006)		<input type="checkbox"/>
40	EN ISO 20743	2013-07	Textiles - Determination of the antibacterial activity of textile products (ISO 20743:2013)		<input type="checkbox"/>
41	EN ISO 6222	1999-05	Water quality - Enumeration of culturable micro-organisms - Colony count by inoculation in a nutrient agar culture medium (ISO 6222:1999)		<input type="checkbox"/>
42	EN ISO 7899-2	2000-04	Water quality – Detection and enumeration of intestinal enterococci - Part 2: Membrane filtration method (ISO 7899-2:2000)		<input type="checkbox"/>
43	EN ISO 9308-1	2014-09	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)		<input type="checkbox"/>
44	Eur.Ph. 2.6.1	2012-01	Testing for microbial contamination in sterile products: enumeration of total, viable, aerobe and anaerobe microorganisms		<input type="checkbox"/>
45	ISO 11731	2017-05	Water quality – Counting of Legionella		<input type="checkbox"/>

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46	ISO 5667-5	2006-04	Water quality — Sampling - Part 5: Guidance on sampling of drinking water from treatment works and piped distribution systems		
5	ISO/TS 15883-5	2005-11	Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy		<input type="checkbox"/>
47	JIS L 1902	2008-10	Testing for antibacterial activity and efficacy on textile products	Chapter 3	<input type="checkbox"/>
48	JIS Z 2801	2012-05	Antimicrobial products-Test for antimicrobial activity and efficacy	Chapter 5	<input type="checkbox"/>
49	OENORM M 6616	1994-03	Water analysis - Determination of temperature		
50	prEN 1656	2017-10	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)		
51	VAH method 14	2015-04	Requirements and methods to the VAH- certified chemical disinfection methods: surface disinfection without mechanics – practical test (method 14)		
52	VAH method 15	2015-04	Requirements and methods to the VAH- certified chemical disinfection methods: chemical/ chemo-thermal disinfection of instruments - practical quantitative germ carrier test (method 15)		

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53	VAH method 17	2015-04	Requirements and methods to the VAH- certified chemical disinfection methods: chemo- thermal laundry disinfection – single bath method (practical test) (method 17)		<input type="checkbox"/>
54	VAH method 7	2015-04	Requirements and methods to the VAH- certified chemical disinfection methods: determination of the bacteriostatic and levurostatic effectiveness as well as suitable neutralizer (method 7)		<input type="checkbox"/>
55	VAH method 8	2015-04	Requirements and methods to the VAH- certified chemical disinfection methods: determination of the bactericidal and yeasticidal effectiveness in a qualitative suspension test (method 8)		<input type="checkbox"/>
56	VAH method 9	2015-04	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)		<input type="checkbox"/>

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1) 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) PvO: test can - if selected - also be done locally.