Bundesministerium für Digitalisierung und Wirtschaftsstandort

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

Typ A-Inspektionsstelle / *Typ A-Inspection Body*

gemäß / *according to*

EN ISO/IEC 17020:2012

Datum der Erstakkreditierung / *Initial date of accreditation*: **18.01.2007**

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.

REPUBLIK ÖSTERREICH Bundesministerium für Digitalisierung und Wirtschaftsstandort

21.06.2018
Datum / *Date*

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

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REPUBLIK ÖSTERREICH 17
Bundesministerium für Digitalisierung und Wirtschaftsstandort

Dipl.-Ing. Dr. Norman Brunner
Wien, am 16. Dezember 2020

Inspection body

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	**2007-01-18**
level 3 accreditation standard according to EA-1/06	**EN ISO/IEC 17020:2012**

Accreditation Austria (AA) is a signatory of the Multilateral Agreement (MLA) of the European co-operation for Accreditation (EA) and of the Mutual Recognition Agreement (MRA) of the International Laboratory Accreditation Cooperation (ILAC) for the accreditation of this accreditation program.
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-3/01:2019 ILAC-P15:2020

Scope of Accreditation of inspection body (EN ISO/IEC 17020:2012)
HygCen Austria GmbH / (ID No.: 0196)

valid from: 2020-12-09

document number [1)] (date of issue)	title of the standard / SOP/ program	type	inspection procedure/ inspection method	scope / scope of application	remarks
21-010 (2015-11)	Hygiene Management System in laundries	type A		site inspection, documentation review, environmental investigation, air technology systems, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection	
21-011 (2014-04)	Hygiene Management System - reprocessing of textile operating room materials - examination of processes and procedures	type A		site inspection, documentation review, environmental investigation, air technology systems, determination of a population of microorganisms on products, thermoelectric examination, examination of process- and program parameters, sterility testing of operation materials used as medical devices for patients, clinic staff and devices,	
21-055 (2014-05)	Hygienic assessment of IVF institutes	type A		site inspection, documentation review, environmental	
21-070 (2014-12)	Site inspection, documentation review, environmental investigation	type A		documentation review, testing of cleaning and disinfection, thermoelectric examination, impression investigation, examination of process- and program parameters	

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valid from: 2020-12-09

document number [1)] (date of issue)	title of the standard / SOP/ program	type	inspection procedure/ inspection method	scope / scope of application	remarks
21-074 (2018-04)	Validation of manual cleaning and manual chemical disinfection of medical devices (guideline 2013)	type A		documentation review, testing of cleaning and disinfection, examination of process- and program parameters	
AK KAB - Arbeitskreis Käfigaufbereitung (2016-01)	Cage processing in animal facilities (5th Edition)	type A	inspections according to chapter 7	documentation review, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection, water analysis	
BGBl. 04/2002 (2002-04)	Hygiene requirements to the structural and functional design and equipment of endoscopy units, RKI	type A		site inspection, documentation review	
BGBl. II Nr. 262/2008 (2008-07)	Regulation of the Minister of Economy and Labor on exercise rules for foot care, cosmetics and massage by professionals	type A	§4, inspection activity to create an inspection report	site inspection, documentation review, environmental investigation, determination of a population of microorganisms on products, sterility of products, thermoelectric examination, biological indicators	
BGesBl. 07/1995 (1995-07)	Hygiene requirements to laundry and washing procedures and conditions for granting of laundry reprocessing to commercial laundries; RKI	type A		site inspection, documentation review, environmental investigation, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection	
EN 13060 (2014-12)	Small steam sterilizers	type A		documentation review, thermoelectric examination, biological indicators	

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EN 14180 (2014-05)	Sterilizers for medical purposes – Low temperature steam and formaldehyde sterilizers – Requirements and testing	type A		documentation review, thermoelectric examination, biological indicators, chemical indicators, desorption review	
EN 16442 (2015-03)	Controlled environment storage cabinet for processed thermolabile endoscopes	type A		documentation review, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection, water analysis	
EN 285 (2015-12)	Sterilization – Steam sterilizers – Large sterilizers	type A		documentation review, thermoelectric examination, measurement of inert gas, water analysis, biological indicators	
EN ISO 11135 (2014-07)	Sterilization of health care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)	type A		documentation review, thermoelectric examination, biological indicators, chemical indicators, regulation for residual gas	
EN ISO 14937 (2009-10)	Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)	type A		among others for hydrogen-peroxide / plasma-method in use; documentation review, thermoelectric examination, biological indicators, chemical indicators, microbiological analysis	
EN ISO 15883-1/A1 (2014-07)	Washer-disinfectors - Part 1: General requirements, definitions and tests (ISO 15883-1:2006 + Amd 1:2014)	type A		documentation review, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection, water analysis	

Scope of Accreditation of inspection body (EN ISO/IEC 17020:2012)
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valid from: 2020-12-09

document number [1)] (date of issue)	title of the standard / SOP/ program	type	inspection procedure/ inspection method	scope / scope of application	remarks
EN ISO 15883-2 (2009-06)	Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. (ISO 15883-2:2006)	type A		documentation review, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection, water analysis	
EN ISO 15883-3 (2009-06)	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO15883-3:2006)	type A		documentation review, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection, water analysis	
EN ISO 15883-6 (2015-08)	Washer-disinfectors – Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment (ISO 15883-6:2011);	type A		documentation review, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection, water analysis	
EN ISO 15883-7 (2016-03)	Washer-disinfectors – Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment (ISO 15883-7:2016)	type A		documentation review, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection, water analysis	
EN ISO 17664 (2017-12)	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664:2004)	type A		documentation review, inspection of cleaning and disinfection, sterilisation and drying	

Scope of Accreditation of inspection body (EN ISO/IEC 17020:2012)
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valid from: 2020-12-09

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EN ISO 17665-1 (2006-08)	Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)	type A		documentation review, thermoelectric examination, water analysis	
KRINKO/BfArM - Richtlinie: Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut (RKI) und des Bundesinstitutes für Arzneimittel und Medizinprodukte (BfArM) (2012-10)	Requirements to hygiene in the reprocessing of medical devices	type A		Only the parts concerning the reprocessing of medical devices; site inspection, documentation review, environmental investigation, air technical systems, determination of a population of microorganisms on products, sterility of products, thermoelectric examination, examination of process- and program parameters, sterility testing of operation materials used as medical devices for patients, clinic staff and devices	
OENORM H 6020 (2015-03)	Ventilation and air condition plants for locations for medical use – Design, construction, operation, maintenance, technical and hygienic inspections	type A	Inspection acc. chapter 5.2 and OENORM H 6020-2, table 1	5.2 und H 6020-2, table 1 site inspection, documentation review, particle measurement, airborne germs measurement, impression investigation, microbiological analysis	

Scope of Accreditation of inspection body (EN ISO/IEC 17020:2012)
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document number [1] (date of issue)	title of the standard / SOP/ program	type	inspection procedure/ inspection method	scope / scope of application	remarks
prEN ISO 15883-4 (2016-05)	Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermo-labile endoscopes (ISO/DIS 15883-4:2016)	type A		documentation review, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection, water analysis	
VDI 6022 Blatt 1 (2018-01)	Ventilation and indoor-air quality - Hygiene requirements for ventilation and air-conditioning systems and units (VDI Ventilation Code of Practice)	type A	Inspection acc. to part 5.3;	site inspection, documentation review, particle measurement, airborne germs measurement, impression investigation, microbiological analysis	

[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.