



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

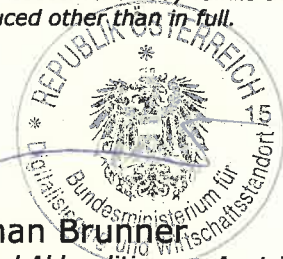
Informationen zum Akkreditierungsumfang und zu Akkreditierung Austria / *Information about the accreditation scope and Akkreditierung Austria* <http://www.bmdw.gv.at/akkreditierung>

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.

21.06.2018
Datum / *Date*


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



inspection body type A

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 **EN ISO/IEC 17020:2012**
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. Accreditation is additionally granted in accordance with the following provisions, which must also be observed in the currently valid version.

other requirements EA-3/01:2013
ILAC-P15:2016

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

valid from: 2018-05-16

No.	document number ¹⁾ of the standard or SOP	date of issue	title of the standard or SOP	product / category (remarks)	conformity assessment procedures / module
1	21-010	2015-11	Hygiene Management System in laundries	Site inspection, documentation review, environmental investigation, air technology systems, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection	
2	21-011	2014-04	Hygiene Management System - reprocessing of textile operating room materials - examination of processes and procedures	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,	
3	21-055	2014-05	Hygienic assessment of IVF institutes	Site inspection, documentation review, environmental investigation	
4	21-070	2014-06	Hygienic examination of reprocessing of dishwashers	documentation review, testing of cleaning and disinfection, thermoelectric examination, impression investigation, examination of process- and program parameters	

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

valid from: 2018-05-16

No.	document number ¹⁾ of the standard or SOP	date of issue	title of the standard or SOP	product / category (remarks)	conformity assessment procedures / module
5	21-074	2018-04	Validation of manual cleaning and manual chemical disinfection of medical devices (Guideline 2013)	documentation review, testing of cleaning and disinfection examination of process- and program parameters	
6	AK KAB- Arbeitskreis Käfigaufbereitung	2016-01	Cage processing in animal facilities (5th Edition)	documentation review, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection, water analysis	Inspection acc. chapter 7
7	BGBI. 04/2002	2002-04	Hygiene requirements to the structural and functional design and apparative equipment of endoscopy units, RKI	Site inspection, documentation review,	
8	BGBI. II No. 262/2008	2008-07	Regulation of the Minister of Economy and Labour on exercise rules for foot care, cosmetics and massage by professionals	Site inspection, documentation review, environmental investigation, determination of a population of microorganisms on products, sterility of products, thermoelectric examination, biological indicators	§4, inspection activity to create an inspection report
9	BGesBl. 07/1995	1995-07	Hygiene requirements to laundry and washing procedures and conditions for granting of laundry reprocessing to commercial laundries; RKI	Site inspection, documentation review, environmental investigation, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection	

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

valid from: 2018-05-16

No.	document number ¹⁾ of the standard or SOP	date of issue	title of the standard or SOP	product / category (remarks)	conformity assessment procedures / module
10	EN 13060	2014-12	Small steam sterilizers	documentation review, thermoelectric examination, biological indicators	
11	EN 14180	2014-05	Sterilizers for medical purposes – Low temperature steam and formaldehyde sterilizers – Requirements and testing	documentation review, thermoelectric examination, biological indicators, chemical indicators, desorption review	
12	EN 16442	2015-03	Controlled environment storage cabinet for processed thermolabile endoscopes	documentation review, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection, water analysis	
13	EN 285	2015-12	Sterilization – Steam sterilizers – Large sterilizers	documentation review, thermoelectric examination, measurement of inert gas, water analysis, biological indicators	
14	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)	documentation review, thermoelectric examination, biological indicators, chemical indicators, regulation for residual gas	

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

valid from: 2018-05-16

No.	document number ¹⁾ of the standard or SOP	date of issue	title of the standard or SOP	product / category (remarks)	conformity assessment procedures / module
15	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)	among others for hydrogen-peroxide / plasma-method in use; Documentation review, thermoelectric examination, biological indicators, chemical indicators, microbiological analysis	
16	EN ISO 15883-1/A1	2014-07	Washer-disinfectors - Part 1: General requirements, definitions and tests (ISO 15883-1:2006 + Amd 1:2014)	documentation review, thermoelectric examination, examination of process- and program parameters, inspection of cleaning and disinfection, water analysis	
17	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)	documentation review, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection, water analysis	
18	EN ISO 15883-3	2009-06	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2006)	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)
HygCen Austria GmbH / (ID No.: 0196)

valid from: 2018-05-16

No.	document number ¹⁾ of the standard or SOP	date of issue	title of the standard or SOP	product / category (remarks)	conformity assessment procedures / module
19	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);	documentation review, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection, water analysis	
20	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)	documentation review, thermoelectric examination, examination of process- and program parameters, testing of cleaning and disinfection, water analysis	
21	EN ISO 17664	2017-12	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices (ISO 17664:2017)	documentation review, testing of cleaning, disinfection, sterilisation and drying	
22	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)	documentation review, thermoelectric examination, water analysis	

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

valid from: 2018-05-16

No.	document number ¹⁾ of the standard or SOP	date of issue	title of the standard or SOP	product / category (remarks)	conformity assessment procedures / module
23	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	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	
24	OENORM H 6020	2015-03	Ventilation and air condition plants for locations for medical use – Design, construction, operation, maintenance, technical and hygienic inspections	5.2 and H 6020-2, table 1 Site inspection, documentation review, particle measurement, airborne germs measurement, impression investigation, microbiological analysis of liquid mediums	Inspection acc. chapter 5.2 and OENORM H 6020-2, table 1
25	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)	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)
HygCen Austria GmbH / (ID No.: 0196)**

valid from: 2018-05-16

No.	document number ¹⁾ of the standard or SOP	date of issue	title of the standard or SOP	product / category (remarks)	conformity assessment procedures / module
26	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)	Site inspection, documentation review, particle measurement, airborne germs measurement, impression investigation, microbiological analysis of liquid mediums	Inspection acc. to part 5.3;

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 indicate.