

# Deutsche Akkreditierungsstelle GmbH

## Annex to the Accreditation Certificate D-PL-17310-01-01 according to DIN EN ISO/IEC 17025:2018

**Valid from: 25.06.2020**

Date of issue: 06.08.2020

Holder of certificate:

**HYBETA GmbH  
Nevinghoff 20, 48147 Münster**

Tests in the fields:

**pharmaceutical products and active agents; health care (hygiene);  
microbiological analyses within the scope of food hygiene; microbiological analysis of surfaces;  
microbiological analyses according to the German Drinking Water Ordinance; sampling of drinking  
water for microbiological, chemical and physical-chemical analyses; sampling and microbiological  
analyses of drinking water, swimming and bathing pool water, cooling water and humidifier water;  
physical analyses of drinking water, swimming and bathing pool water, cooling water and humidifier  
water;  
sampling and microbiological analysis of industrial water in accordance with the German ordinance  
on evaporative cooling systems, cooling towers and wet separators – Section 3 (8) 42nd BImSchV  
2017**

**fields of testing:** hospital hygiene, microbiological-hygienic tests, biological analysis of pharmaceutical products, active agents and excipients

For the test methods marked with \*, the testing laboratory is permitted to freely select standard test methods or equivalent methods without obtaining prior notification and consent from Deutsche Akkreditierungsstelle GmbH (DAkKS GmbH).

For the test methods marked with \*\*\*, the testing laboratory is permitted to use standards or equivalent testing methods listed here with different issue dates without obtaining prior notification and consent from Deutsche Akkreditierungsstelle GmbH (DAkKS GmbH).

The test methods listed are given by way of an example. The laboratory has an up-to-date list of all test methods within the flexible scope of accreditation

**This document is a translation. The definitive version is the original German annex to the accreditation certificate.**

Abbreviations used: see last page

*The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.  
<https://www.dakks.de/en/content/accredited-bodies-dakks>*

## 1. Field: Health care (hygiene)

### 1.1 Field of testing: Hospital hygiene

#### Type of test: Cultural methods\*

Standard / date of issue In-house method /version	Analytics - Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
MIQ 22/2005 Chapter 3.3.3	Hospital hygiene testing Part I - Analysis of other liquids	Aqueous solutions
VAH (Association for Applied Hygiene) recommendation 2013 Hyg. Med. 2013; 38 – 6 MIQ 23/2018 Chapter 12	Hospital hygiene testing Part I - Analysis of disinfectant samples from disinfectant dosing systems	Disinfectant solution
VAH recommendation 2013 Hyg Med 2013; 38 – 3	Control measures when using wipe-dispenser systems for surface disinfection depending on the risk profile	Disinfectant solutions from wipe-dispenser systems
DIN EN ISO 23500-4:2019-11	Preparation and quality management of fluids for haemodialysis and related therapies - Part 4: Concentrates for haemodialysis and related therapies	Dialysis water
DIN EN ISO 23500-3:2019-11	Production and quality management of fluids for haemodialysis and related therapies - Part 3: Water for haemodialysis and related therapies	Dialysis water
DIN EN ISO 23500-5:2019-11	Production and quality management of fluids for haemodialysis and related therapies - Part 5: Quality of liquids for haemodialysis and related therapies	Dialysis water
Guideline for applied hygiene in dialysis, 3rd edition, 2013	Analysis of dialysis water	Dialysis water
DIN EN 16442 2015-05	Controlled environment storage cabinet for processed thermolabile endoscopes - Degree of contamination on the inner surfaces, microbial contamination	Contact samples/plates, rinsing solution/swab
VAH: Disinfectants Commission, Hyg.Med., 2011, 36-7/8, p.309-310	Detection methods regarding the bacterial load of washing machines / washing goods	Rinse water, raw water, water after softening

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Standard / date of issue In-house method /version	Analytics - Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
VAH: Disinfectants Commission, Hyg.Med. 2015,40-4, p.159	Monitoring of laundry disinfection using germ carriers (biomonitors, bioindicators)	Detergent solution, contact plates, bioindicators (contaminated cotton cloths)
DIN 10113-2 1997-07	Determination of surface colony count on fitment and utensils in foodareas - Part 2: Semiquantitative swab method <i>(Deviation: only in the context of hospital hygiene)</i>	Contact plates, swabs
DIN 10113-3 1997-07	Determination of surface colony count on fitment and utensils in foodareas - Part 3: Semiquantitative method with sampling devices coated with nutrient medium (contact method) <i>(Deviation: only in the context of hospital hygiene)</i>	Contact plates, swabs
DIN SPEC 10534 2019-02	Food hygiene - Commercial dishwashing - Hygiene requirements, testing <i>(Deviation: only in the context of hospital hygiene)</i>	Metal germ carrier contaminated with RAMS solution and E. faecium ATCC 6057, cleaning solution; contact plates
Guidelines for hospital hygiene and infection prevention 4.4.3 and 6.4 - Hospital laundry, laundry services/contracting to commercial laundries Federal Health Service 7/95	Hygiene requirements for laundry from health service facilities, laundry and washing operations and conditions for contracting laundry to commercial laundries	Rinse water, raw water, water after softening, cleaning solution, contact plates, bioindicators (contaminated cotton cloths)

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**Type of test: Cultural methods**

Standard / date of issue In-house method /version	Analytics - Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
SOP LAB-092 A	Analysis of dialysis fluid according to GAMBRO	Dialysis water
SOP-THB-022_RLT B	Drying chamber test	Contact samples/ plates, rinsing solution/swab

**1.2 Field of testing: Microbiological-hygienic tests**

**Type of test: Cultural methods\***

Standard / date of issue In-house method /version	Analytics - Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
DIN EN ISO 14698 –1 2004-04 Appendix C	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods	Surfaces
MIQ 23/2005, Chapter 8	Microbiological quality control in pharmaceutical production	Surfaces

**Type of test: Test for endotoxins\***

Standard / date of issue In-house method /version	Analytics - Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
Ph.Eur. 9, Chapter 2.6.14 D	Test for bacterial endotoxins	Dialysis water, rinse water

**Type of test: Cultural methods**

Standard / date of issue In-house method /version	Analytics - Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
AM-LAB-001 C	Microbiological analysis of bioindicators in the context of disinfecting and chemo-thermal cleaning processes	Bioindicators, cleaning indicators
AM-LAB-007 E	Microbiological analysis of bioindicators from hot air sterilizers	Bioindicators (spore strips)

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AM-LAB-024 I	Protein-chemical testing of cleaning processes	Cleaning indicators
SOP-THB-014 B	RRT-Qualification measurement	Surfaces
SOP-LAB-006 B	GMP-Environmental monitoring	Contact plates, swabs
SOP-THB-014 B	RRT-Qualification measurement double!	Contact plates, swabs
AM-LAB-079 C	General environmental monitoring	Contact plates, swabs

**Type of test: Germ-content determination and physical determinations of air and gases\***

Standard / date of issue In-house method /version	Analytics - Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
DIN EN 16442 2015-05	Controlled environment storage cabinet for processed thermolabile endoscopes - Determination of air exchange rate, degree of contamination on internal surfaces, maintenance of endoscope condition, drying function, air-quality, moisture content, oil content, particle contamination, airborne microbial contamination, temperature control, duct ventilation test	Air velocity, residual moisture/temperature, relative humidity, particles, air germ count (impaction)
VDI 4300 Gazette 10 2008-07	Measurement of indoor air pollution - Measurement strategies for the detection of indoor mold <i>(Deviation: only in the context of health-care provision)</i>	Air (culture media from airborne-germ collection devices)
MIQ 22/2005, Chapter 6	Hygiene acceptance of RLT (ventilation and air-conditioning technology) systems	Air (culture media from airborne germ samplers)
DIN EN ISO 14698-1 2004-04, Appendix A, B and C	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods	Air (sedimentation plates, culture media from airborne-germ collection devices)

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MIQ 22/2005 Chapter 6	Hygiene acceptance of RLT (ventilation and air-conditioning technology) systems	Air (sedimentation plates, culture media from airborne-germ collection devices)
MIQ 23/2005 Chapter 8	Microbiological quality control in pharmaceutical production	Air (sedimentation plates, culture media from airborne-germ collection devices)
DIN 1946-4 2008-12, Appendices B (visual preliminary examination) and C (measurement of degree of protection)	Ventilation and air conditioning - Part 4: Ventilation in buildings and rooms of health care	fog-visualized flow direction, airborne particles, air velocity, and temperature
DIN EN ISO 14644-1 2016-06	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration	Airborne particles
DIN EN ISO 14644-3 2006-03	Cleanrooms and associated controlled environments - Part 3: Test methods	Airborne particles

**Type of test: Germ-content determination and physical determinations of air and gases\***

<b>Standard/date of issue In-house method /version</b>	<b>Analytics - Title of the Standard or the in-house method (specify any deviations / modifications of standard method)</b>	<b>Test item</b>
SOP-LAB-006 B	GMP-Environmental monitoring	Sedimentation plates
SOP-THB-014 B	RRT-Qualification measurement	Sedimentation plates
AM-LAB-079 C	General environmental monitoring	Sedimentation plates
SOP-THB-014 B	Clean room-Qualification measurement	Air (sedimentation plates, culture media from airborne-germ collection devices)
SOP-THB-007_RLT_RRT B	Measurement of relative air humidity	relative humidity of air
SOP-THB-001_RLT_RRT B	Measurement of particle count	Airborne particles
SOP-THB-021_RLT_RRT A	Measurement of flow speed	Air velocity
SOP-THB-004_RLT_RRT B	Measurement of volume flow	Air-flow volume

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<b>Standard/date of issue In-house method /version</b>	<b>Analytics - Title of the Standard or the in-house method (specify any deviations / modifications of standard method)</b>	<b>Test item</b>
SOP-THB-010_RLT A	Temperature measurement	Air temperature
SOP-THB-003_RLT_RRT B	Leak test on the installed filter system	Airborne particles
SOP-THB-006_RLT_RRT B	Recovery time measurement	Airborne particles
SOP-THB-011_RLT A	Visual preliminary examination	Flow behavior (flow visualization)
SOP-THB-011_RLT A	Degree of protection measurement	Protective effect (airborne particles, air velocity and temperature)
SOP-THB-005_RLT_RRT A	Pressure difference measurement	Pressure difference
SOP-THB-013_RLT A	Testing of operating theatres Particle counts, airborne-germ concentration measurements, verification of the flow direction, creation of a flow and temperature profile for ventilated ceilings	Airborne particles, culture media from airborne-germ collection devices, flow visualization, air velocity and temperature

**2 Scope: pharmaceutical products and active agents**

**2.1 Testing area: Biological analysis of pharmaceutical products, active agents and excipients**

**Type of test: Sterility testing**

<b>Standard / date of issue In-house method /version</b>	<b>Analytics - Title of the Standard or the in-house method (specify any deviations / modifications of standard method)</b>	<b>Test item</b>
PIC/S Document 007-6 2011/01	"Recommendation on the Validation of Aseptic Processes"	Mediafill
DIN EN ISO 13408-1 2015-12:	Aseptic processing of health care products - Part 1: General requirements	Mediafill

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**Type of test: Microbiological analysis of non-sterile products\***

Standard / date of issue In-house method /version	Analytics - Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
Ph.Eur. 9, Chapter 2.6.12	Determination of total germ count (TAMC, TYMC)	Non-sterile products
Ph.Eur. 9, Chapter 2.6.13	Detection of specified microorganisms	Non-sterile products

**Type of test: Microbiological analysis of non-sterile products**

Standard / date of issue In-house method /version	Analytics - Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
SOP-LAB-090 A	Microbiological analysis of dialysis water, dialysis fluid, bicarbonate and acid concentrate	Bicarbonate/acid

**Type of test: Test for bacterial endotoxins\***

Standard / date of issue In-house method /version	Analytics - Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
Ph.Eur. 9, Chapter 2.6.14 D	Test for bacterial endotoxins	Bicarbonate/acid

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### 3 Microbiological analysis of surfaces

VDI 6022-1 2011-07, Chapter 8.3.1	Ventilation and air-conditioning technology, indoor air-quality hygiene requirements for ventilation systems and equipment (here: <i>microbiological analysis of contact plates (surfaces)</i> )
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### 4 Microbiological analyses in the context of food hygiene

DIN 6650-8:2009-12	Dispense systems for draught beverages - Part 8: Requirements for point of use water coolers
DIN 6650-9:2010-09	Dispense systems for draught beverages - Part 9: Watercoolers
SOP LAB-042 C	Dispensing equipment

### 5 Sampling of drinking water, swimming and bathing pool water, cooling water, and humidifier water

DIN EN ISO 19458(K19): 2006-12	Water quality - sampling for microbiological analyses
UBA (Federal Environment Agency) recommendation 2018-12-18	Recommendation of the Federal Environment Agency after consulting the Drinking Water Commission: Systemic examination of drinking water installations according to the Drinking Water Ordinance - sampling, examination procedure, and result declaration (here sections 4 and 5).
UBA (Federal Environment Agency) recommendation 2018-12-18	Recommendation of the Federal Environment Agency after consulting the Drinking Water Commission of the Federal Ministry of Health at the Federal Environment Agency: Assessment of drinking water quality with regard to lead, copper, and nickel parameters
DIN 19643-1 2012-11	Treatment of water of swimming pools and baths - Part 1: General requirements
VDI 2047 Gazette 2 2019-03	VDI (Association of German Engineers) guideline for re-cooling plants - ensuring the hygienic operation of evaporation cooling systems  (here: <i>Section 9.3.2 Microbiological analyses</i> )
UBA (Federal Environment Agency) recommendation 2017-06-02	Recommendation of the Federal Environment Agency on the sampling and detection of legionella in evaporation cooling systems, cooling towers, and water separators, sections C and D

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VDI 6022-1  
2018-01

Ventilation and air-conditioning technology, indoor air-quality hygiene requirements for ventilation systems and equipment  
(here: *Chapter 8* Measurement procedures and analyses during hygiene controls and hygiene inspections)

### 6 Microbiological analyses of swimming and bathing pool water, and humidifier water \*\*\*

TrinkwV (Drinking Water Ordinance) section 15 (1c)

Quantitative determination of cultivatable microorganisms

DIN EN ISO 6222 (K5)  
1999-07

Water quality - Quantitative determination of cultivable micro-organisms - Determination of colony count by inoculation in a culture medium

DIN EN ISO 7899-2 (K 15)  
2000-11

Water quality - Detection and enumeration of intestinal enterococci - Part 2: Membrane filtration method

DIN EN ISO 9308-1 (K12)  
2017-09

Water quality - Enumeration of Escherichia coli and coliform bacteria - Part 1: Membrane filtration method for waters with low bacterial background flora

DIN EN ISO 16266 (K11):  
2008-05

Water quality - Detection and enumeration of Pseudomonas aeruginosa - Method by membrane filtration

DIN EN ISO 11731 2019-03

Water quality - Enumeration of Legionella

UBA (Federal Environment Agency) recommendation  
2018-12-18

Recommendation of the Federal Environment Agency after consulting the Drinking Water Commission: Systemic examination of drinking water installations according to the Drinking Water Ordinance - sampling, examination procedure, and result declaration (here sections 6, 7 and 8)

VDI 6022-1  
2018-01

Ventilation and air-conditioning technology, indoor air-quality hygiene requirements for ventilation systems and equipment  
(here: *Chapter 8* Measurement procedures and analyses during hygiene controls and hygiene inspections)

### 7 Physical analyses of drinking water, swimming and bathing pool water, cooling water, and humidifier water

DIN 38404-C 4  
1976-12

Determination of Temperature

-Translation-

## 8 Test Methods in Accordance with the German Drinking Water Ordinance – Trinkwasserverordnung (TrinkwV)\*\*\*

### Sampling of Drinking Water

Method	Title
DIN EN ISO 19458 (K19) 2006-12	Water quality - Sampling for microbiological analysis
UBA (Federal Environment Agency) recommendation 2018-12-18	Recommendation of the Federal Environment Agency after consulting the Drinking Water Commission of the Federal Ministry of Health at the Federal Environment Agency: Assessment of drinking water quality with regard to lead, copper, and nickel parameters
UBA (Federal Environment Agency) recommendation 2018-12-18	Recommendation of the Federal Environment Agency after consulting the Drinking Water Commission: Systemic examination of drinking water installations according to the Drinking Water Ordinance - sampling, examination procedure, and result declaration (here sections 4 and 5).

### APPENDIX 1: MICROBIOLOGICAL PARAMETERS

#### Part I: General Requirements for Drinking Water

Seq. no.	Parameter	Method
1	Escherichia coli (E. coli)	DIN EN ISO 9308-1 (K12): 2017-09
2	Enterococcus	DIN EN ISO 7899-2 (K15): 2000-11

#### Part II: Requirements for drinking Water intended for transfer in sealed containers

Seq. no.	Parameter	Method
1	Escherichia coli (E. coli)	DIN EN ISO 9308-1 (K12): 2017-09
2	Enterococcus	DIN EN ISO 7899-2 (K15): 2000-11
3	Pseudomonas aeruginosa	DIN EN ISO 16266 (K11): 2008-05

### APPENDIX 2: CHEMICAL PARAMETERS

#### Part I: Chemical parameters, whose concentration not usually increase in the Distribution Network, including the Building Installation

Not documented

#### Part II: Chemical parameters, whose concentration may increase in the Distribution Network, including the House Installation

Not documented

### APPENDIX 3: INDICATOR PARAMETERS

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**Part I: General Indicator parameters**

Seq. no.	Parameter	Method
1	Aluminium	Not documented
2	Ammonium	Not documented
3	Chloride	Not documented
4	Clostridium perfringens (including spores)	DIN EN ISO 14189 (K24) 2016-11
5	Coliform bacteria	DIN EN ISO 9308-1 (K12) 2017-09
6	Iron	Not documented
7	Colouring (Spectral Absorption Coefficient Hg 436 nm)	Not documented
8	Odor (as TON)	EN ISO 1622(B3) 2006-10 (Appendix C)
9	Taste	Not documented
10	Colony count at 22 °C	TrinkwV (Drinking Water Ordinance) Section 15 (1c) DIN EN ISO 6222 1999-07
11	Colony count at 36°C	TrinkwV (Drinking Water Ordinance) Section 15 (1c) DIN EN ISO 6222 1999-07
12	Electrical conductivity	DIN EN 27888:1993-11 (C8)
13	Manganese	Not documented
14	Sodium	Not documented
15	Organically bound carbon (TOC)	Not documented
16	Oxidisability	Not documented
17	Sulphate	Not documented
18	Turbidity	Not documented
19	Hydrogen ion concentration	DIN EN ISO 10523: 2012-04
20	calcite dissolving capacity	Not documented

**Part II: Special Requirements for Drinking Water in Systems in the Drinking Water Installation**

Parameter	Method
Legionella spec.	ISO 11731: 2017-05 UBA recommendation 18. December 2018

**APPENDIX 3a: Requirements for Drinking Water with Regard to Radioactive Substances**

Not documented

**Parameters not included in Annexes 1 to 3 of the 2011 German Drinking Water Ordinance**

**Additional Periodic Testing**

Not documented

*The accreditation does not replace the recognition or approval procedure of the competent authority pursuant to § 15 (4) TrinkwV.*

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**9 Sampling and microbiological analysis of industrial water in accordance with the German ordinance on evaporative cooling systems, cooling towers and wet separators – Section 3 (8) 42nd BImSchV 2017\*\*\***

**Sampling**

Method	Titel
DIN EN ISO 19458 (K 19) 2006-12	Water quality - Sampling for microbiological analysis  ----- Recommendation of the German Federal Environmental Agency (UBA Umweltbundesamt) for the sampling and detection of Legionella in evaporative cooling systems, cooling towers and wet separators of 02.06.2017, sections C und D

**Microbiological testing**

Parameter	Verfahren
Legionella	ISO 11731 2017-05  ----- Recommendation of the German Federal Environmental Agency (UBA Umweltbundesamt) on the sampling and detection of Legionella in evaporative cooling systems, cooling towers and wet separators of 02.06.2017, sections E und F taking into account attachment 1 and 2
Colony count at 22°C and 36 °C	DIN EN ISO 6222 (K 5) 1999-07

**abbreviations used:**

ADKA	Bundesverband Deutscher Krankenhausapotheker e.V. (Federal Association of German Hospital Pharmacists)
AMG	Arzneimittelgesetz (German Medicines Act)
DIN	Deutsches Institut für Normung e.V. (German Institute for Standardization)
EN	Europäische Norm (European standard)
FDA	Food and Drug Administration
GMP	Good Manufacturing Practice
ISO	Institut für Normung (Institute for Standardization)
MiQ	Mikrobiologische-infektiologische Qualitätsstandards (Microbiological and infectiological quality standards)
Ph. Eur.	Pharmacopoea Europaea (European Pharmacopoeia)
RKI	Robert Koch Institute
SOP	Standard Operating Procedure
TrinkwV	Trinkwasserverordnung (Drinking Water Ordinance)

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