



INTERNATIONAL ACCREDITATION KEEP SERVICE

ACCREDITATION CERTIFICATE

MEDİCERT ULUSLAR ARASI ÜRÜN VE SİSTEM BELGELENDİRME BAĞIMSIZ
DENETİM VE EĞİTİM HİZM. LTD. ŞTİ.

Tersane Mah. Yalı Caddesi No: 11/3 Karşıyaka / İZMİR / TÜRKİYE

As a result of the audit conducted by the IAKS, it is accredited in the annexes to the ISO /IEC 17025-1:2017
General requirements for the competence of testing and calibration laboratories standard,

Accreditation Number: IAKS-TL-1018

Accreditation Date: 02.01.2025

This certificate is valid until 02.01.2026 if the above mentioned name and address continue to comply with the relevant standards, international and regional rules in addition to the written organizations ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories standard,


This certificate is given by IAKS. The certificate becomes invalid in case of suspension and cancellation of accreditation.

For current accreditation information visit www.iaks.us or communicate with IAKS on info@iaks.us

CONFIRMATION

Attachment of Accreditation certificate


SCOPE OF ACCREDITATION

 <p>MANAGEMENT SYSTEM ISO/IEC 17025-1:2017 IAKS-TL-1018</p>	IAKS ACCREDITED NUMBER	IAKS-TL-1018
	COMPANY NAME	MEDICERT ULUSLAR ARASI ÜRÜN VE SİSTEM BEL. BAĞIMSIZ DENETİM VE EĞİTİM HİZMETLERİ LTD. ŞTİ.
	ADRESS	TERSANE MAH. YALI CADDESİ NO:11/3 KARŞIYAKA – İZMİR / TÜRKİYE
	CONTACT NAME	EROL ÜSTÜN
	TELEPHONE	0 232 327 33 44
	ACCREDITATION DATE	02.01.2025
	ACCREDITATION STANDARD	ISO/IEC 17025:2017

ACCREDITATION AREA:	General requirements for the competence of testing and calibration laboratories	
ACCREDITATION STANDARD:	ISO/IEC 17025:2017	
Scope of Test		
Test material/ Products	Experiment Name	Test Method
Simulators and monitoring systems(MDS,BMS) Microbiologic hygienic tests	Testing to prove applicability of Batch Monitoring Systems (BMS)	--
Sterile barrier and packing systems Materials Microbiologic hygienic tests	Tests in the context of proving compliance Compatibility to sterilisation with Moist heat Dry heat	DIN EN ISO 11607-1 DIN EN 868-5
	Tests to prove compliance Stability of the heat sealed joint -Colour change of the process indicator of plastic laminated film for capillary holes -Peel characteristics of paper-plastic-laminates -Suitability for storage and transport	DIN EN ISO 11607-1 DIN EN 868-5 DIN EN 868-5 DIN EN ISO 11140-1 DIN EN 868-5 DIN EN 868-5 DIN EN 868-5

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Scope of Test		
Test material/ Products	Experiment Name	Test Method
Medical devices, Information for reprocessing Microbiologic hygienic tests including physicals tests	Test in the context of validation on the basis of provided information Sterilization with -Hydrogene peroxide -Drying -Packaing/Storing	DIN EN 556
Biological indicators Microbiologic hygienic tests	Test to prove compliance -Vitality -Population determination of spore suspensions -Population determination of spores on solid carriers -Purity	DIN EN ISO 11138-1
	D-value determination and evaluation of bioindicators for sterilization processes using -Moist heat -Ethylene oxide -Low temperature steam-and formaldehyde -Dry heat	DIN EN ISO 11138-3 DIN EN ISO 11138-2 DIN EN ISO 11138-5 DIN EN ISO 11138-4

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Scope of Test		
Test material/ Products	Experiment Name	Test Method
Medical devices Microbiologic hygienic tests	Testing the resistance of reference germs depending and sterilization with -Moist heat -Dry heat -Ethylene oxide -Low temperature steam and formaldehyde(NTOF)	DIN EN ISO 11138-3 DIN EN ISO 11138-4 DIN EN ISO 11138-2 DIN EN ISO 11138-5
	Test to prove compliance -Vitality -Population determination of spore suspensions -Population determination of spores on solid carriers -Purity	DIN EN ISO 11138-1 DIN EN ISO 14161
	Sterility test Membrane filtration Direct inoculation	DIN EN 11737-2

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Scope of Test		
Test material/ Products	Experiment Name	Test Method
Medical devices Biologic materials Microbiologic Hygienic tests	Estimation of the population of microorganisms on products (Bioburden determination) -Membrane filtration method -Spread plate method -Pour plate method	DIN EN ISO 11737-1
Biological Indicators Microbiologic Hygieic tests	D-value determination and evaluation of bioindicators for sterilization processes using	DIN EN ISO 14161 DIN EN ISO 11138-1 DIN EN ISO 18472
Test systems Chemical indicators Microbiologic Hygienic tests	Test to prove compliance in Sterilization processes using -Moist heat -Dry heat -Ethylene oxide-Low-temperature-steam and formaldehyde -Hydrogene peroxid	DIN EN ISO 11140-1 DIN EN ISO 11140-3 DIN EN ISO 11140-4 ISO 11140-5 DIN EN 20187 DIN EN ISO 18472
Simulators and monitoring systems (MOS,BMS) Microbiologic hygienic tests	Testing to prove applicability of Bowie-Dick-Simulation Tests -Test devices according EN 867-5 -Test devices according DIN EN 1422 -Medical Device -Simulators(MDS)	DIN EN ISO 11140-4 DIN EN 867-5 DIN EN 1422 DIN 58921

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Scope of Test		
Test material/ Products	Experiment Name	Test Method
Mechanical and physical properties Respiratory protective devices –Filtering half masks to protect against particies	In House Method SOP:MC.149	EN 149:2001+A1:2009
Performance requierements and tests Protective Clothing	Compressive Properties in In-Plande Direction	ISO 14126:1999/AC:2002

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Scope of Test		
Test material/ Products	Experiment Name	Test Method
Biocidal Products	Determination Method of the Povidone Iodine Concentration	European Pharmacopoeia 7.0, 01/2008:1142 sayfa:2778-2779
Biocidal Products	Determination Method of the Ethanol (Chromatographic Method GC)	European Pharmacopoeia 7.0, 01/2008:1318, pages:1966-1967
Biocidal Products	Determination Method of the Isopropanol (Chromatographic Method GC)	European Pharmacopoeia 7.0, 01/2008:1318, pages:1966-1967
Biocidal Products	Determination Method of the Hydrogen Peroxide Concentration	European Pharmacopoeia 7.01 01/2008:0396, page:2202
Biocidal Products	Determination Method of the Sodium Hypochlorite Concentration	Directive 98/8/EC Concerning the placing of biocidal products on the market, (2010, March). Sodium Hypochlorite Product-type PT 1,2,3,4 and 5 Powell Fabrication&Manufacturing, Inc. (2014). The Bleach Strength Test-A Chemical Test Method to Determine the Strength of Sodium Hypochlorite
Biocidal Products	Determination Method of the Benzalkonium Chloride Concentration (Chromatographic Method HPLC)	European Pharmacopoeia 7.0, 04/2009:0371, page:1463-1464

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Scope of Test		
Test material/ Products	Experiment Name	Test Method
Biocidal Products	Determination Method of the Tricloroisocyanuric Acid Concentration	TAPPI(1997).Analysis of bleaching Konsantrasyonu powder,calcium,hypochlorite bleach sludge Use of Chloroisocyanuarates for Disinfection of Water:Application of Miscellaneous General Chemistry Topics.Gabriel Pinto and Brian,RohrigJournal of Chemical Education 2003 80 (1),41
Biocidal Products	Determination Method of the Sodium Dricloroisocyanurate (dihydrate) Cocentration	TAPPI(1997).Analysis of bleaching powder,calcium,hypoch lo rite bleach Metodu liquor, and bleach sludge Use of Chloroisocyanuarates for Disinfection of Water:Application of Miscellaneous General Chemistry Topics.Gabriel Pinto and Brian,RohrigJournal of Chemical Education 2003 80 (1),41

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Scope of Test		
Test material/ Products	Experiment Name	Test Method
Biocidal Products	Determination Method the Calcium Hypochlorite Concentration	Directive 98/8/EC Concerning the placing of biocidal products on the market,(2010,March).Sodium Hypochlorite Product-type PT 1,2,3,4 and 5 Powell Fabrication&Manufacturing,Inc. (2014).The Bleach Strength Test-A Chemical Test Method to Determine the Strength of Sodium Hypochlorite TAPPI(1997).Analysis of bleaching power,calcium hypochlorite bleach liquor,and bleach sludge
Biocidal Products	Determination Method the Iodine Concentration	European Pharmacopoeia 7.0 01/2008:0031,page 2261
Biocidal Products	Determination Method the Sodium dichloroisocyanurate (anhydrous) Concentration	TAPPI(1997).Analysis of bleaching powder,calcium,hypochlorite bleach liquor, and bleach sludge Use of Chloroisocyanurates uaretes for Disinfection of Water:Application of Miscellaneous General Chemistry Topics.Gabriel Pinto and Brian,RohrigJournal of Chemical Education 2003 80 (1),41
Drug Tests	Stability Testing of Existing Active Ingerdents and Related Finished Products	CPMP/QWP/122/02
	Quality of Biotechnological Products: Stability Testing of Biotechnological / biological products	ICH Q5C (CPMP/ICH/138/95) July 1996
	Guidelines on Allergenic Products: Production and Quality Issues	EMA/CHMP/BWP/304831/2007, May 2009

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Scope of Test		
Test material/ Products	Experiment Name	Test Method
Biocidal Products	Determination Method of the Tetrabutylammonium Hydrogen Sulfate Concentration	-
Biocidal Products	Chlorhexidine Digluconate Concentration Determination Method	European Pharmacopoeia 7.0
Biocidal Products	Determination Method of the Decidyl Dimethyl Ammonium Chloride Concentration	-
Chemical disinfectants and antiseptics	Chemical disinfectants and antiseptics-quantitative suspension experiment-For evaluation of bacterial killing effectiveness in the medical field- Test method and requierments (phase 2,step 1)	TS EN 13727+A2,March 2016
Chemical disinfectants and antiseptics	Chemical disinfectants and antiseptics-used in medicine virus killing quantitative suspension test for chemical disinfectants and antiseptics-Test method and requirements (phase 2, step 1)	TS EN 14476+A1,March 2016

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Scope of Test		
Test material/ Products	Experiment Name	Test Method
Chemical disinfectants and antiseptics	Chemical disinfectants and antiseptics- Food,indusü,household and used in industrial areas chemical disinfectants and fungus formation in antiseptics or fermentation evaluation-Experiment method and requirements (phase2,step 1)	TS EN 1650:2008+Al:2013, December 2013
Chemical disinfectants and antiseptics	Chemical disinfectants and antiseptics- Antiseptics in the medical field-Quantitative suspension test for the evaluation of the fungicidal effectiveness of chemical disinfectants used in devices used in the medical field-Test method and requirements (phase 2,step 1)	TS EN 13624, February 2014
Medical devices	Irritation,Sensitization,Cytotoxicity,Implantation,Subchronic Toxicity,Subacute Toxicity,Genotoxicity,Pyrogenicity,Biocompatibility Test	ISO 10993 TS EN 455-3 OECD 471 OECD 487

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Scope of Test		
Test material/ Products	Experiment Name	Test Method
Medical Device	1.Shelf Life Test 2.Packaging Sealing 3.Packaging Durability 4.Determination of Residual Ethylene Oxide 5.Drawing the Residual Ethylene Oxide Cruve 6.Determination of Residual Ethylene Chlorhydrin 7.Detergent Residue Determination 8. Detergent Residue Determination 9.Oil Residue 10.Antibacterial Efficiency Test / Antibacterial Effectiveness on Nonporous Surfaces 11. Antibacterial Efficiency Testing in Industrial Type Disinfectants (Microbiological+Chemistry) 12.Sterility test-Medical device 13.Biological load test (Aerobic + fungus + Aner ob) 14.Biological load test (Anerob) 15.Biological load test(Aerobic + mushroom Dose determination) 16.Biological load test (Aerobic + mushroom + Anae rob Validation) 17.Corrosion Test for Hand Tools Used in Surgery and Dentistry 18.Corrosion Test for Catheters other Than Intravenous Catheters 19.Corrosion Test for Intravenous Catheters	ASTM F 1980 ASTM F 1929 EN 868-5 ISO 10993-7 ISO 10993-7 ISO 10993-7 TS EN ISO 2271 ASTM F 2459-18 SM 5520-B TS EN ISO 22196 TS EN ISO 1276 ISO 11737-2 ISO 11737-1 ISO 11737-1 ISO 11737-1 ISO 11737-1 TS 5172 EN ISO 13402 TS EN 1618 BS EN ISO 10555-1
Software used in device manufacturing and measuring machines and equipment	Medical device software validation	ISO 80002-1 ISO 80002-2

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Scope of Test		
Test material/ Products	Experiment Name	Test Method
Electrical Medical Device	Radiated Emission-Electromagnetic Field Electrostatic Discharge-ESD Immune to Radiated RF Distortions	TS EN 60601-1-2:2011 TS EN 55011:2010 Group1 ClassB TS EN 61000-4-2:2014

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Scope of Test		
Test material/ Products	Experiment Name	Test Method
Medical&Surgical Gowns and Drapes	Microbial penetration resistance(wet)	ISO 22610:2018
	Microbial penetration resistance(dry)	EN ISO 22612:2005
	Microbial evaluation(bioburden)	ISO 11737-1:2018(Bioburden method)
	Particle evaluation	EN ISO 9073-10:2004
	Liquid penetration reistance	EN ISO 811:2018
	Burst strength	EN ISO 13938-1:2019
	Tensile Strength	EN 19073-3:1992
	Ethylene Oxide(EO) Residual Analysis	ISO 10993-7:2008/AMD 1:2019

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Scope of Test		
Test material/ Products	Experiment Name	Test Method
Medical gloves for single use	Requirements and testing for physicals properties	EN 455-2
Medical gloves for single use	Requirements and testing for biological evaluation	EN 455-3
Protective gloves against dangerous chemicals and micro-organisms	Determination of resistance to penetration	EN ISO 374-2
Protective gloves against dangerous chemicals and micro-organisms	Determination of resistance to degradation by chemicals	EN ISO 374-4

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Scope of Test		
Test material/ Products	Experiment Name	Test Method
Medical gloves for single use	Selection of conditions and test methods	EN 1186-1:2002
	Aqueous food simulants by total immersions method	EN 1186-3:2002
	Aqueous food simulants by article method	EN 1186-9:2002
	Olive oil by total immersion method	EN 1186-2:2002
	Olive oil by total article method	EN 1186-8:2002
	Substitute test	EN 1186-14:2002
	Test methods for overall migration into mixtures of C-labelled synthetic triglycerides	EN 1186-11

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ACCREDITATION STANDARD:	ISO/IEC 17025:2017	
Scope of Test		
Test material/ Products	Experiment Name	Test Method
Medical gloves for single use	Standard Specification for Nitrile Examination	ASTM D6319-10
	Standard Test Method for Residual Powder	ASTM D6124-06
	Standard Test Method for Detection of Holes	ASTM D5151-19
	Standart Practicefor Assessment of Resistance of Medical Glovesto Permeation by Chemotherapy Durgs	ASTM D6978-05
	Test methods fo r overall migration into mixtures Of C-labelled synthetic triglycerieds	TS EN 1186-11
	Standard Specification for Poly(vinyl chloride)	ASTM D5250-19