


Attachment of Accreditation certificate


SCOPE OF ACCREDITATION

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|  <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 | Mansuro lu Mah. 286/1 Sk. No: 1 ç Kapı No: 101 Bayraklı / zmir/ TÜRKİYE |
| | CONTACT NAME | EROL ÜSTÜN |
| | TELEPHONE | 0 232 327 33 44 |
| | ACCREDITATION DATE | 02.01.2026 |
| | ACCREDITATION STANDARD | ISO/IEC 17025:2017 |

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| 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) | -- |
| Sterille barrier and packing systems Meterials Microbiologic hygienic tests | Tests in the context of proving compliance Compatibility to sterilisation with Moist heat Dry heat Validation and routine control of moist heat sterilization processes | DIN EN ISO 11607-1 DIN EN 868-5 DIN EN ISO 17665-1:2024 |
| | Tests to prove compliance Stability of the heat sealed joint -Colour change of the process indicator of plastic laminated film for capilla ry holes -Peel characteristics of paper-pla stic-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 |
| Medical Devices | D-value determination and evaluation of bioindicators for sterilization processes using -Moist heat -Ethylene oxide -Low temperature steam-and formaldehyde -Dry heat Validation and routine control of moist heat sterilization processes | DIN EN ISO 11138-3 DIN EN ISO 11138-2 DIN EN ISO 11138-5 DIN EN ISO 11138-4 DIN EN ISO 17665-1:2024 |
| Biological indicators | -A guide to the selection, use, and interpretation of results for the validation and monitoring of sterilization processes. - Specific requirements for biological indicator systems and process challenge devices designed for use in air purge tests. | DIN EN ISO 11138-6 DIN EN ISO 11138-7 DIN EN ISO 11138-8 |

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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 Validation and routine control of moist heat sterilization processes | DIN EN 11737-2 DIN EN ISO 17665-1:2024 |
| Biological indicators | -A guide to the selection, use, and interpretation of results for the validation and monitoring of sterilization processes. - Specific requirements for biological indicator systems and process challenge devices designed for use in air purge tests. | DIN EN ISO 11138-6 DIN EN ISO 11138-7 DIN EN ISO 11138-8 |

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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 Validation and routine control of moist heat sterilization processes | 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 DIN EN ISO 17665-1:2024 |
| 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 |
| Material Testing | Application of inductively coupled plasma mass spectrometry (ICP-MS) | EN ISO 17294-2:2023 |

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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 |

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| Biocidal Products | Determination Method of the Sodium Dricloroisocyanurate (dihydrate) Cocentration | TAPPI(1997).Analysis of bleaching powder,calcium,hypoch lomite 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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| ACCREDITATION STANDARD: | | ISO/IEC 17025:2017 |
| 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 o 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 |

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| Biocidal Products | Determination Method the Sodium dichloroisocyanurate (anhydrous) Concentration | TAPPI(1997).Analysis of bleaching powder,calcium,hypochlorite bleach liquor, and bleach sludge Use of Chloroisocyanuarates uarettes 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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| ACCREDITATION STANDARD: | | ISO/IEC 17025:2017 |
| 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 | - |

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| 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+A1:2013, December 2013 |

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| 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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| Test material/ Products | Experiment Name | Test Method |

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| Medical Device | <ol style="list-style-type: none"> 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. Validation and routine control of moist heat sterilization processes 14.Biological load test (Aerobic + fungus + Aner ob) 15.Biological load test (Anerob) 16.Biological load test(Aerobic + mushroom Dose determination) 17.Biological load test (Aerobic + mushroom + Anae rob Validation) 18.Corrosion Test for Hand Tools Used in Surgery and Dentistry 19.Corrosion Test for Catheters other Than Intravenous Catheters 20.Corrosion Test for Intravenous Catheters | <p>ASTM F 1980 ASTMF 1929 EN 868-5 ISO 10993-7 ISO 10993-7 ISO 10993-7 TS EN ISO 2271 ASTMF 2459-18 SM 5520-B TS EN ISO 22196 TS EN ISO 1276 ISO 17665-1:2024 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</p> |
| Software used in device manufacturing and measuring machines and equipment | Medical device software validation | <p>ISO 80002-1 ISO 80002-2</p> |
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| Test material/ Products | Experiment Name | Test Method |

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| Electrical Medical Device | <p>Radiated Emission-Electromagnetic Field Electrostatic Discharge-ESD Immune to Radiated RF Distortions</p> <p>Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems</p> | <p>TS EN 60601-1-2:2011 TS EN 55011:2010 Group1 ClassB TS EN 61000-4-2:2014</p> <p>TS EN 62133-2</p> |
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| Scope of Test | | |
| Test material/ Products | Experiment Name | Test Method |

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| 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 | |

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| | COMPANY NAME | MEDICERT ULUSLAR ARASI ÜRÜN VE SİSTEM BEL. BAĞIMSIZ DENETİM VE EĞİTİM HİZMETLERİ LTD. ŞTİ. |
| | ADRESS | Mansuro lu Mah. 286/1 Sk. No: 1 ç Kapı No: 101 Bayraklı / zmir / TÜRKİYE |
| | CONTACT NAME | EROL ÜSTÜN |
| | TELEPHONE | 0 232 327 33 44 |
| | ACCREDITATION DATE | 02.01.2026 |
| | ACCREDITATION STANDARD | ISO/IEC 17025:2017 |

| 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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| ACCREDITATION AREA: | General requirements for the competence of testing and calibration laboratories |
| ACCREDITATION STANDARD: | ISO/IEC 17025:2017 |
| Scope of Test | |

Attachment of Accreditation certificate

SCOPE OF ACCREDITATION


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|  <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 | Mansuro lu Mah. 286/1 Sk. No: 1 ç Kapı No: 101 Bayraklı / zmir / TÜRKİYE |
| | CONTACT NAME | EROL ÜSTÜN |
| | TELEPHONE | 0 232 327 33 44 |
| | ACCREDITATION DATE | 02.01.2026 |
| | ACCREDITATION STANDARD | ISO/IEC 17025:2017 |

| 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 AREA: | General requirements for the competence of testing and calibration laboratories |
| ACCREDITATION STANDARD: | ISO/IEC 17025:2017 |
| Scope of Test | |

Attachment of Accreditation certificate

SCOPE OF ACCREDITATION


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|  <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 | Mansuro lu Mah. 286/1 Sk. No: 1 ç Kapı No: 101 Bayraklı / zmir / TÜRKİYE |
| | CONTACT NAME | EROL ÜSTÜN |
| | TELEPHONE | 0 232 327 33 44 |
| | ACCREDITATION DATE | 02.01.2026 |
| | ACCREDITATION STANDARD | ISO/IEC 17025:2017 |

| 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 |

| Test material/ Products | Experiment Name | Test Method |
|-------------------------|---|---|
| Drug Tests | | |
| | | |
| | Determination method of relative potency with IgG | IgG Potency Assays on Polymerised and Depot Polymerised Extracts (ES-QCTP050) |

Attachment of Accreditation Certificate


SCOPE OF ACCREDITATION

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|  <p>MANAGEMENT SYSTEM ISO/IEC 17020:2012 IAKS-TL-1018</p> | IAKS ACCREDITATION NUMBER | IAKS-TL-1018 |
| | COMPANY NAME | MEDİCERT ULUSLARARASI ÜRÜN VE SİSTEM BELGELENDİRME BAĞIMSIZ DENETİM VE EĞİTİM HİZMETLERİ LİMİTED ŞİRKETİ |
| | ADRESS | Mansuro lu Mah. 286/1.Sk. No: 1 ç Kapı No: 101 Bayraklı / zmir - TÜRKİYE |
| | CONTACT NAME | EROL ÜSTÜN |
| | TELEPHONE | 0 232 3273344 |
| | ACCREDITATION DATE | 02.01.2026 |
| | ACCREDITATION STANDARD | ISO/IEC 17020:2012 |

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| Accreditation Area | Clean Rooms, Related Controlled Environments and Ventilation Systems | |
| Accreditation Standard | ISO/IEC 17020:2012 | |
| Certification Sectors | | |
| Inspection Area | Inspection Type | Standard / Specification |
| <p>16.1. HVAC Systems of Operating Rooms, Intensive Care Units and Other Hospital Hygienic Areas</p> <ul style="list-style-type: none"> - Measurement of Air Flow, Air Velocity and Uniformity - Measurement of Pressure Difference - Hepa And Ulpa Filter Equipment Leak Test - Content leak testing - Particle Counting and Cleanroom Classification - Temperature and Humidity Measurement - Visualization of Air Flow Direction and Air Flow Characteristics - Determination of Recovery Time - Measurement of Protection Degree or Turbulence Intensity | <p>16.A. First Inspection 16.B. Periodic Inspection</p> | <p>ISO 14644-1 ISO 14644-2 ISO 14644-3 IEST-RP-CC006 IEST-RP-CC034 D N 1946-4 ASHRAE170</p> |
| <p>16.2. Production Areas, Laboratories, Laminar Air Flow Areas</p> <ul style="list-style-type: none"> - Measurement of Air Flow, Air Velocity and Uniformity - Measurement of Pressure Difference - Hepa And Ulpa Filter Equipment Leak Test - Content leak testing - Particle Counting and Cleanroom Classification - Temperature and Humidity Measurement - Visualization of Air Flow Direction and Air Flow Characteristics - Determination of Recovery Time | <p>16.A. First Inspection 16.B. Periodic Inspection</p> | <p>EudraLex Volume 4 Annex 1 GMP Medicinal Products for Human and Veterinary Use FDA cGMP-Sterile Drug Products Produced by Aseptic Processing ISO 14644-1 ISO 14644-2 ISO 14644-3 IEST-RP-CC006 IEST-RP-CC034</p> |

Attachment of Accreditation Certificate

SCOPE OF ACCREDITATION

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|  <p>MANAGEMENT SYSTEM ISO/IEC 17020:2012 IAKS-TL-1018</p> | NAC ACCREDITATION NUMBER | IAKS-TL-1018 |
| | COMPANY NAME | MEDİCERT ULUSLARARASI ÜRÜN VE SİSTEM BELGELENDİRME BAĞIMSIZ DENETİM VE EĞİTİM HİZMETLERİ LİMİTED ŞİRKETİ |
| | ADRESS | Mansuro lu Mah. 286/1,Sk. No: 1 ç Kapı No: 101 Bayraklı / zmir - TÜRKİYE |
| | CONTACT NAME | EROL ÜSTÜN |
| | TELEPHONE | 0 232 3273344 |
| | ACCREDITATION DATE | 02.01.2026 |
| | ACCREDITATION STANDARD | ISO/IEC 17020:2012 |

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| Accreditation Area | Clean Rooms, Related Controlled Environments and Ventilation Systems | |
| Accreditation Standard | ISO/IEC 17020:2012 | |
| Certification Sectors | | |
| Inspection Area | Inspection Type | Standard / Specification |
| 16.3. Biosafety Cabinets - Down Airflow Velocity Measurement - Intake Air Flow Rate Measurement - Hepa and Ufpa Filter Equipment Leakage Test - Air Flow Direction and Visualization - Control of Alarm and Other Functions | 16.A. First Inspection 16.B. Periodic Inspection | TS EN 12469 NSF/ANSI-49 IEST-RP-CC034 |
| 16.4 Laminar Airflow Cabinets - Air Flow Rate Measurement - Hepa and Ulpa Filter Equipment Leakage Test - Air Flow Direction and Visualization - Particle Count | 16.A. First Inspection 16.B. Periodic Inspection | TS EN ISO 14644-1 TS EN ISO 14644-2 TS EN ISO 14644-3 IEST-RP-CC006 IEST-RP-CC034 IEST-RP-CC002 |
| 16.6 Fume Hoods - Control of Alarm and Other Functions - Air Flow Direction and Visualization - Intake Air Flow Rate Measurement - Volumetric Tensile Flow Rate Measurement - Room Air Velocity Measurement | 16.B. Periodic Inspection | TS EN 14175-1 TS EN 14175-2 TS EN 14175-3 TS EN 14175-4 TS EN 14175-6 |
| 16.7 Ventilation and Air Conditioning Systems 16.7.1 Tightness and Strength Test in Rectangular Ventilation Ducts 16.7.2 Tightness and Strength Test in Circular Ventilation Ducts | 16.A. First Inspection | TS EN 1507 TS EN 12237 ANSI/SMACNA-016 BESA/DW 143 |