



TURKISH ACCREDITATION AGENCY

ACCREDITATION CERTIFICATE

As a Testing Laboratory

BIÇAKÇILAR TIBBİ CİHAZLAR SANAYİ VE TİCARET ANONİM ŞİRKETİ

Central Address: OSMANGAZİ MAH. GAZİ CAD. BIÇAKÇILAR NO:21 ESENYURT İstanbul / Türkiye

is accredited in accordance with TS EN ISO/IEC 17025:2017 standard within the scope given in Annex following the assessment conducted by TURKAK.

Accreditation Number : AB-0052-T

Accreditation Date : 14.03.2006

Revision Date / Number : 26.06.2024 / 19

This certificate shall remain in force until **28.11.2026**, subject to continuing compliance with the standard **TS EN ISO/IEC 17025:2017**, related regulations and requirements.

Gülden Banu Müderrisoğlu
Secretary General



Turkish Accreditation Agency (TURKAK) is a signatory to the European co-operation for Accreditation (EA) Multilateral Agreement (MLA) and International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA) in the scope of ISO/IEC 17025.

This document has been signed by Gülden Banu Müderrisoğlu with a secure electronic signature in accordance with the electronic signature law numbered 5070. Use the QR code to verify the e-signed document.

 <p>Test TS EN ISO/IEC 17025 AB-0052-T</p>	BIÇAKÇILAR TIBBİ CİHAZLAR SANAYİ VE TİCARET ANONİM ŞİRKETİ	
	Accreditation Nr: AB-0052-T Revision Nr: 19 Date: 26.06.2024	
Testing Laboratory		
Address : OSMANGAZI MAH. GAZI CAD. BIÇAKÇILAR NO:21 ESENYURT İstanbul / Türkiye	Phone : +90 212 689 0220 Fax : - Email : eozturk@bicakcilar.com Website :	

Medical Devices		
Tested Materials / Products	Name of Test	Testing Method (National, International Standards, In-house Methods)
Medical Product (Excluding Contact with Cerebrospinal Fluid)	Bacterial Endotoxin (LAL) Test Gel Cloth Method	USP 42 NF 37 European Pharmacopoeia 2.6.14 (Method A)
Medical Products (Excluding Contact with Cerebrospinal Fluid)	Bacterial Endotoxin Test Kinetic Turbidimetric Method	USP 42 NF 37 European Pharmacopoeia 2.6.14 (Method C)
Medical Devices	Sterility Test	ISO 11737-2
Medical Devices	Determination of a population of microorganisms on health care products (Bioburden Testing)	ISO 11737-1
Medical Devices/Polymeric and Elastomeric Plastics	In vitro Cytotoxicity Test	ISO 10993-5 ISO 10993-12
Surgical and Dental Hand Instruments	Corrosion Test Boiling Water Method	TS 5172 EN ISO 13402
Intravascular Catheters	Corrosion Test Salt Water Method	TS EN ISO 10555-1
Medical Materials and Related Products	Determination of Residual Ethylene Oxide (C ₂ H ₄ O) GC-FID / HS (Headspace) Method	ISO 10993-7
Medical Materials and Related Products	Determination of Residual Ethylene Chlorhydrin (HOCH ₂ CH ₂ Cl) GC-FID / HS (Headspace) Method	ISO 10993-7
Metallic Medical Components	Determination of Residual Oil-Grease Pre-Treatment: Extraction Method Determination: Gravimetric Method	ASTM F2459
Metallic Medical Components	Determination of Residual Detergent Pre-Treatment: Extraction Method Determination: Gravimetric Method	ASTM F2459
Medical Devices	Sterility Test	USP 42 NF 37 European Pharmacopoeia 2.6.1
Enteral Feeding Systems	Corrosion Test Salt Water Method	TS EN ISO 20695 Annex-B

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Revision Nr: 19 Date: 26.06.2024

Plastic and Rubber Products

Tested Materials / Products	Name of Test	Testing Method (National, International Standards, In-house Methods)
Polymer Based Electrotechnical Products	Determination of Phthalate (BBP,DBP,DEHP,DIBP) GC-MS Method	IEC 62321-8
Polymer Based Electrotechnical Products	Determination of Lead (Pb), Mercury (Hg), Cadmium (Cd), Total Chromium (Cr) ICP-OES Method	IEC 62321-5
Polymer Based Electrotechnical Products	Determination of Mercury (Hg) ICP-OES Method	IEC 62321-4
Polymer Based Electrotechnical Products	Determination of Cr(VI) in Polymers and Electronics UV-VIS Spectrophotometer Method	IEC 62321-7-2
Polymer Based Electrotechnical Products	Determination of PBB (Poly Brominated biphenyl ethers) PBDE (Poly Brominated diphenyl ethers) GC-MS Method	IEC 62321-6

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Drugs, Biological Products and Pharmaceuticals		
Tested Materials / Products	Name of Test	Testing Method (National, International Standards, In-house Methods)
Medicines (Parenteral Solutions Excluding Antibiotics)	Sterility Test	European Pharmacopiea 2.6.1

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Products and Materials of Metals and Alloys		
Tested Materials / Products	Name of Test	Testing Method (National, International Standards, In-house Methods)
Metals	Determination of Mercury (Hg) ICP-OES Method	IEC 62321-4
Metals	Determination of Lead (Pb), Cadmium (Cd) ICP-OES Method	IEC 62321-5
Metals	Presence of hexavalent chromium (Cr(VI)) in colourless and coloured corrosion-protected coatings on metals by the colorimetric method UV-VIS Spectrophotometer Method	IEC 62321-7-1

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Textile and Leather Products		
Tested Materials / Products	Name of Test	Testing Method (National, International Standards, In-house Methods)
Textiles	Evaluation of Antimicrobial Activity	AATCC 100
Textiles	Standard Test Method for Determining the Antimicrobial Activity of Antimicrobial Agents under Dynamic Contact Conditions	ASTM E2149
Textiles	Determination of Antibacterial Activity Absorption Method	ISO 20743
Textiles	Determination of Antimicrobial Activity	JIS-L 1902
Textiles	Determination of Antibacterial Activity Parallel Streak Method	AATCC 147
Textiles	Antifungal Assessment Mildew Resistance Test Test III Agar Plate Method	AATCC 30
Textiles	Determination of Antibacterial Activity Agar Diffusion Test	ISO 20645
Textile,Plastic,Metal,Medical Device,Paper-Cardboard Packaging,Ceramic-Glass,Wood	Evaluation of Antibacterial Activity and Efficacy	JIS Z 2801
Plastic (on Non-porous Materials)	Determination of Antibacterial Activity	ISO 22196

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