



TURKISH ACCREDITATION AGENCY

ACCREDITATION CERTIFICATE

As a Management System Certification Body

KAREV ULUSLARARASI TIBBİ VE TEKNİK BELGELENDİRME ANONİM ŞİRKETİ

Central Address: MUSTAFA KEMAL MAH. 2136 SK. NO:6 ÇANKAYA Ankara / Türkiye

is accredited in accordance with TS EN ISO/IEC 17021-1:2015 standard within the scope given in Annex following the assessment conducted by TURKAK.

Accreditation Number : AB-0180-YS

Accreditation Date : 08.03.2023

Revision Date / Number : 08.03.2023 / 00

This certificate shall remain in force until **07.03.2027**, subject to continuing compliance with the standard **TS EN ISO/IEC 17021-1:2015**, 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 Accreditation Forum (IAF) MLA in the scope of ISO/IEC 17021-1.


This document has been signed by Gülden Banu Müderrisoğlu on {1} 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>Medical Devices M.S. TS EN ISO/IEC 17021-1 AB-0180-YS</p>	<p style="text-align: center;">KAREV ULUSLARARASI TIBBİ VE TEKNİK BELGELENDİRME ANONİM ŞİRKETİ</p> <p style="text-align: center;">Accreditation Nr: AB-0180-YS Revision Nr: 00 Date: 08.03.2023</p> <p>Management System Certification Body</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <p>Address : MUSTAFA KEMAL MAH. 2136 SK. NO:6 ÇANKAYA Ankara / Türkiye</p> </td><td style="width: 50%; vertical-align: top;"> <p>Phone : +90 312 444 4882 Fax : - Email : serdargezer@karevcert.com Website : www.karevcert.com</p> </td></tr> </table>	<p>Address : MUSTAFA KEMAL MAH. 2136 SK. NO:6 ÇANKAYA Ankara / Türkiye</p>	<p>Phone : +90 312 444 4882 Fax : - Email : serdargezer@karevcert.com Website : www.karevcert.com</p>
<p>Address : MUSTAFA KEMAL MAH. 2136 SK. NO:6 ÇANKAYA Ankara / Türkiye</p>	<p>Phone : +90 312 444 4882 Fax : - Email : serdargezer@karevcert.com Website : www.karevcert.com</p>		

TS EN ISO 13485:2016 Medical Devices Management System Certification

Main Technical Area	Technical Area
Non-active Medical Devices	General Non-active, Nonimplantable Medical Devices
Non-active Medical Devices	Non-active Implants
Non-active Medical Devices	Devices for Wound Care
Non-active Medical Devices	Non-active Dental Devices and Accessories
Active Medical Devices (Non-implantable)	General Active Medical Devices
Active Medical Devices (Non-implantable)	Devices for Imaging
Active Medical Devices (Non-implantable)	Monitoring Devices
Active Medical Devices (Non-implantable)	Devices for Radiation Therapy and Thermo Therapy
In Vitro Diagnostic Medical Devices (IVD)	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry, Immunochemistry (Immunology), Haematology / Haemostasis / Immunohematology, Microbiology, Infectious Immunology, Histology / Cytology, Genetic Testing
In Vitro Diagnostic Medical Devices (IVD)	In Vitro Diagnostic Instruments and Software
Sterilization Method for Medical Devices	Ethylene Oxide Gas Sterilization (EOG)
Sterilization Method for Medical Devices	Moist Heat
Sterilization Method for Medical Devices	Aseptic Processing
Sterilization Method for Medical Devices	Radiation Sterilization (e.g. Gamma, X-ray, Electron Beam)
Sterilization Method for Medical Devices	Thermic Sterilization with Dry Heat



<div></div> <div>Medical Devices M.S. TS EN ISO/IEC 17021-1 AB-0180-YS</div>	KAREV ULUSLARARASI TIBBİ VE TEKNİK BELGELENDİRME ANONİM ŞİRKETİ	
	Accreditation Nr: AB-0180-YS Revision Nr: 00 Date: 08.03.2023	
	Management System Certification Body	
	Address : MUSTAFA KEMAL MAH. 2136 SK. NO:6 ÇANKAYA Ankara / Türkiye	Phone : +90 312 444 4882 Fax : - Email : serdargezer@karevcert.com Website : www.karevcert.com
Devices Incorporating / Utilizing Specific Substances / Technologies	Medical Devices Incorporating Medicinal Substances	
Devices Incorporating / Utilizing Specific Substances / Technologies	Medical Devices Utilizing Micromechanics	
Devices Incorporating / Utilizing Specific Substances / Technologies	Medical Devices Utilizing Nanomaterials	
Devices Incorporating / Utilizing Specific Substances / Technologies	Medical Devices Utilizing Biological Active Coatings and/or Materials or Being Wholly or Mainly Absorbed	
Devices Incorporating / Utilizing Specific Substances / Technologies	Medical Devices Incorporating or Utilizing Specific Substances / Technologies / Elements Other Than Specified Above	
Parts or Services	Raw Materials	
Parts or Services	Components	
Parts or Services	Subassemblies	
Parts or Services	Calibration Services	
Parts or Services	Distribution Services	
Parts or Services	Maintenance Services	
Parts or Services	Transportation Services	
Parts or Services	Other Services	

This document has been signed by Gülden Banu Müderrisoğlu on {1} with a secure electronic signature in accordance with the electronic signature law numbered 5070. Use the QR code to verify the e-signed document.

