



TURKISH ACCREDITATION AGENCY

## ACCREDITATION CERTIFICATE

As a Management System Certification Body,

**NOTİCE BELGELENDİRME MUAYENE VE DENETİM  
HİZMETLERİ A.Ş**

**ESENTEPE MAHALLESİ MİLANGAZ CADDESİ 75 A/92 KARTAL  
İSTANBUL / TURKEY**

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-0127-YS**

**Accreditation Date : 17 October 2016**

**Revision Date / Number : 02 June 2022 / 04**


This certificate shall remain in force until **16 October 2024**, subject to continuing compliance with the standard **TS EN ISO/IEC 17021-1:2015**, related regulations and requirements.



*G. Banu MÜDERRİSOĞLU*  
**G. Banu MÜDERRİSOĞLU**  
Secretary General

Turkish Accreditation Agency (TURKAK) is a signatory to the European co-operation for Accreditation (EA) Multilateral Agreement (MLA) in the scope of ISO/IEC 17021.

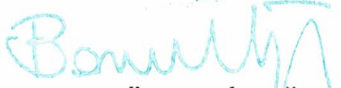
Annex of the certificate (Page 1/1)  
Accreditation Scope

 Tıbbi Cihazlar K. Y. S. TS EN ISO/IEC 17021-1 AB-0127-YS	<b>NOTİCE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ A.Ş</b>	
	Accreditation Nr: AB-0127-YS Revision Nr: 04 Date: 02 June 2022	
	TS EN ISO 13485: 2016 Medical Devices - QMS Requirements for regularity purposes	
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* EA Code	Description
Non-active Medical Devices	General non-active, non-implantable medical devices Non-active implants Devices for wound care Non-active dental devices and accessories Non-active medical devices other than specified above
Active Medical Devices (Non-Implantable)	General active medical devices Monitoring devices Devices for radiation therapy and thermo therapy Active (non-implantable) medical devices other than specified above
Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG) Moist heat Aseptic processing Radiation sterilization (e.g. gamma, x-ray, electron beam)
Devices incorporating/utilizing specific substances/technologies	Medical devices incorporating medicinal substances Medical devices utilizing micromechanics Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above
Devices incorporating/utilizing specific substances/technologies	Medical devices utilizing nanomaterials
Parts or Services	Raw materials Components Subassemblies Distribution services Maintenance services Transportation services Other services

END of SCOPE



  
**G. Banu MÜDERRİSOĞLU**  
Secretary General