



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 : 15 October 2020 / 02

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
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	NOTİCE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ A.Ş	
	Accreditation Nr: AB-0127-YS Revision Nr: 02 Date: 15 October 2020	
TS EN ISO 13485: 2016 Medical Devices - QMS Requirements for regularity purposes		
Address : ESEANTEPE MAHALLESİ MİLANGAZ CADDESİ 75 A/92 KARTAL İSTANBUL/TÜRKİYE		Phone :0216 504 16 98 Fax :- E-Mail :namiye@notice.com.tr Website :notice.com.tr

* 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

END of SCOPE



Banültepe

G. Banu MÜDERRİSOĞLU
Secretary General