



TURKISH ACCREDITATION AGENCY

ACCREDITATION CERTIFICATE

As a Management System Certification Body

NOTİCE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ ANONİM ŞİRKETİ

Central Address: ESENTEPE MAH. MİLANGAZ CAD. MONUMENTO KARTAL A BLOK NO:75 A/92 KARTAL İstanbul / 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-0127-YS

Accreditation Date : 17.10.2016

Revision Date / Number : 13.08.2024 / 05


This certificate shall remain in force until **15.10.2028**, 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 with a secure electronic signature in accordance with the electronic signature law numbered 5070. Use the QR code to verify the e-signed document.

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|  <p>Medical Devices M.S. TS EN ISO/IEC 17021-1 AB-0127-YS</p> | NOTİCE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ ANONİM ŞİRKETİ | |
| | Accreditation Nr: AB-0127-YS Revision Nr: 05 Date: 13.08.2024 | |
| Management System Certification Body | | |
| Address : ESENTEPE MAH. MİLANGAZ CAD. MONUMENTO KARTAL A BLOK NO:75 A/92 KARTAL İstanbul / Türkiye | Phone : +90 216 504 1698 Fax : - Email : namiye@notice.com.tr Website : www.notice.com.tr | |

| 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 |
| Non-active Medical Devices | Non-active Medical Devices Other Than Specified Above |
| Active Medical Devices (Non-implantable) | General Active Medical Devices |
| Active Medical Devices (Non-implantable) | Monitoring Devices |
| Active Medical Devices (Non-implantable) | Devices for Radiation Therapy and Thermo Therapy |
| Active Medical Devices (Non-implantable) | Active (Non-implantable) Medical Devices Other Than Specified Above |
| 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) |
| 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 |



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| Parts or Services | Raw Materials | |
| Parts or Services | Components | |
| Parts or Services | Subassemblies | |
| Parts or Services | Distribution Services | |
| Parts or Services | Maintenance Services | |
| Parts or Services | Transportation Services | |
| Parts or Services | Other Services | |

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