



# CERTIFICATE

Certification No : 00108/DÖR13A  
Initial Certification Date : 20.01.2010  
Recertification Date : 07.01.2022  
Issue Date : 07.01.2022  
Expiration Date : 19.01.2023  
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RoyalCert, certifies that the management system of the organization has been assessed and found to be in accordance with the requirements of the related standard.

## ISO 13485:2016

### DÖRT-A TIP MALZEMELERİ SANAYİ İTHALAT İHRACAT TİCARET LİMİTED ŞİRKETİ

Balikhisar Mahallesi, Köy İçi Serpmeleri, No:795/A, Akyurt, Ankara, TURKEY

**Scope:** Production, Design, Assembly and Packaging of Sterilization Reels and bags, Self Adhesive Sterilization Pouches, Bowie-Dick Test Packages, Indicator Strips ( H2O2 Indicator Strip, Formaldehyde Indicator Strip, Ethylene Oxide Indicator Strip, Dry heat Indicator Strip, Type 4 Indicator Strip, Type 5 Indicator Strip, Type 6 Indicator Strip ), Type 5 Integrator, Rapid Steam Biological Indicator, Longtime Steam Biological Indicator, Ethylene Oxide Biological Indicator, H2O2 ( Plasma ) Biological Indicator, Helix Group Tests, PCD Group Tests, Ethylene Oxide Load Control test, Autoclave Tapes (Steam, Ethylene Oxide, Plasma, Formaldehyde), ESU Pencils, ESU Pencil Tip Cleaner, Wrap and Crepe Paper Sheets, Drainage Systems for Body-Wound Liquid Wastes (Catheters, Storage Bottles), Polypropylene Mesh, Sterile Container System, Container Label, Container Seal, Container Filter, Documentation Labels with Indicator, Reel Barcode Labels with Indicator, Washer Disinfectors, Ultrasonic Devices and Washing Control Tests of Surgical Instruments (Pro Test, Hemo Tests, Washer Test, Cannula Control Test, Sonicontrol Test ), Double Biological Indicator Test Package (Biological Indicator- Type 5 Integrator), Double Load Control Test Package (Type 5 Integrator and Inner PCD Type 6 Indicator), Triple Biological Indicator Test Package (Biological Indicator, Type 5 Integrator and Inner PCD Type 6 Indicator) and Packaging, of Disposable Medical Products

#### General Manager



This certification was conducted in accordance with the RoyalCert auditing and certification procedures and is subject to regular surveillance audits.  
The original certificate contains a security hologram.  
Certification period is 3 years Verifiable at: [www.royalcert.com](http://www.royalcert.com)  
This certification can be verified on TÜRKAK BDS no. and TBDS.turkak.org.tr

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