



# CERTIFICATE

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 13485:2012**

**DÖRT-A TIP MALZEMELERİ SAN. İTH. İHR. TİC. LTD. ŞTİ.**

Balıkhisar Mahallesi Köyiçi Serpmeleri No:795/A

Akyurt / ANKARA

TÜRKİYE

## Scope

Production, Design, Assembly and Packaging of Sterilization Reels (Flat, Tyvek, Gusseted) and bags, Self Adhesive Sterilization Pouches, ESU Pencils, ESU Pencil Tip Cleaner, Bowie-Dick Test Packages, Indicator Strips ( H2O2 Indicator Strip, Formaldehyde Indicator Strip, Ethylene Oxide Indicator Strip, Dry heat Indicator Strip, Class 4 Indicator Strip, Class 5 Indicator Strip, Class 6 Indicator Strip ), Class 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), Wrap and Crepe Paper Sheets, Sterile Container System, Container Label, Container Seal, Container Filter, Documentation Labels with Indicator, Reel Barcode Labels with Indicator; Drainage Systems for Body-wound waste liquids (Catheters, Collecting Bottles), Polypropylene Mesh, Qxygen Masks Systems, 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- Class 5 Integrator), Double Load Control Test Package (Class 5 Integrator and Inner PCD Class 6 Indicator), Triple Biological Indicator Test Package (Biological Indicator, Class 5 Integrator and Inner PCD Class 6 Indicator) Vaginal Speculum (Small-Medium-Large), and Production, Packaging, Marketing And Sales of Disposable Medical Products

**Certification No** : 108/DÖR13A

**Initial Certification Date** : 20.01.2010

**Issue Date** : 22.12.2017

**Expiration Date** : 19.01.2019

**Revision Date – No** : 22.12.2017-00

**Head of Certification**

