



# Sertifika/Certificate

**ISO 13485:2016 SERTİFİKA KAPSAM EK'İ /**  
**ISO 13485:2016 CERTIFICATE SCOPE ADDENDUM**

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

**BALIKHİSAR MAHALLESİ, KÖY İÇİ SERPMELERİ, NO:795/A, AKYURT,**  
**ANKARA, TÜRKİYE / İSTANBUL**

Design, Production and Sales of Sterilization Efficiency Control Products, (Helix Load Control Test, PCD Load Control Test, Ethylene Oxide Control Load Test, Autoclave Tapes (Steam, Ethylene Oxide, Plasma, Formaldehyde, Dry Air), Bowie-Dick Test Packages, Dual Biological Indicator Test Package (Biological Indicator-Type 5 Integrator), Dual Control Load Test Package (Type 5 Integrator and PCD indicator), Triple Biological Indicator Test Package (Biological Indicator, Type 5 Integrator and Type 6 Indicator in PCD), Documentation Labels with Indicators (Steam, Ethylene Oxide, H2O2(Plasma), Dry Air), Steam and Ethylene Oxide Round Adhesive Label, Long-Term Biological Indicators (Steam, Ethylene Oxide, H2O2(Plasma))), Short-Term Biological Indicators (Steam, Ethylene Oxide, H2O2 (Plasma)), Indicator Cards (H2O2 (Plasma), Formaldehyde indicator Cards, Ethylene Oxide indicator Cards, Dry Air indicator Cards, Class 4 indicator Cards, Class 5 indicator Cards, Class 6 indicator Cards, Indicator Roll Barcode Labels, Washing Efficiency Control Products - Design, Production and Sales of Washing Control Tests of Ultrasonic Devices and Surgical Instruments (Protest, Hemotest, Washertest, Glass Washertest, PLS, Cannulacontrol Test, Sonicontrol Test, Aluminum Sonicontrol Test, Aluminum Washer Test, Plastic Washer Test, Plastic Sonicontrol Test), Design, Production and Sales of Packaging Products (Wrap and Crepe Papers, Sterilization Rolls (Plain, Gusseted, Tyvek and Reinforced) and Envelopes (Plain, Gusseted, Tyvek, Self-Adhesive, Reinforced, Self-Adhesive Reinforced, Gamma, Header Bag), Sterile Container Systems, Accessories and Equipment Design, Production and Sales, Container Label, Container Lock, Container Filter, Medical Device Design, Production and Sales, (Cautery Pens, Cautery Sandpaper, Drainage Systems for Body-Wound Waste Fluids (Catheters, Total Bottles), Surgical Instrument Protective Materials, Steam Autoclave Rust Remover Solution, Autoclave Device Seal Lubricant Design, Production and Sales, Sterilization Control Label Gun, Steam and Ethylene Oxide Marker, Incubator, Polypropylene Net Sales

### **KAPSAM ING**

Sertifika No/ Certificate No : IQM-UK-TC-8364  
Sertifika İlk Yayın Tarihi/ Certificate Initial Issue Date : 20.05.2025  
Sertifika Yayın Tarihi/ Certificate Issue Date : 20.05.2025  
Sertifika Geçerlilik Tarihi/ Certificate Validity Date : 19.05.2026



**GENEL MÜDÜR**  
**GENERAL MANAGER**

