



Certificate

DÖRT-A TIP MALZEMELERİ SANAYİ İTHALAT İHRACAT TİCARET LİMİTED ŞİRKETİ

BALIKHİSAR MAH.KÖY İÇİ SERPMELERİ NO:795/A
AKYURT/ ANKARA/ TÜRKİYE

The IQM Certification approves that the above mentioned organization evaluates the Medical Devices Quality Management System and complies with the requirements of the relevant standard

ISO 13485:2016

Scope,

Production, Design, Assembly and Packaging of Sterilization Reels and Pouches, Self Adhesive Sterilization Pouches, Gamma Sterilization Pouch, Header Bag, Bowie-Dick Test Packages, A4 Bowie-Dick, Indicator Strips (H2O2 Plasma 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 Biological Indicators (Steam, Ethylene Oxide, H2O2 (Plasma)), Longtim Biological Indicators (Steam, Ethylene Oxide, H2O2 (Plasma)), Helix Load Control Tests, PCD Load Control Tests, Ethylene Oxide Load Control Test, Autoclave Tapes (Steam, Ethylene Oxide, Plasma, Formaldehyde, Dry Heat), ESU Pencils, ESU Pencil Tip Cleaner, Wrap and Crepe Paper Sheets, Drainage Systems for Body-Wound Liquids (Catheters, Bottles/Reservoirs), Polypropylene Mesh, Sterile Container System, Label Gun, Steam and Ethylene Oxide Marker, Incubator, Steam and Ethylene Oxide Dot Sticker, Container Label, Container Seal, Container Filter, Documentation Labels with Indicator, Instrument Protector, Reel Barcode Labels with Indicator, Washer Disinfectors, Washing Control Tests of Ultrasonic Devices and Surgical Instruments (Pro Test, Hemo Tests, Washer Test, PLS, Cannula Control Test, Sonicontrol Test, Aluminum Sonicontrol Test and Aluminum Washer Test) Double Biological Indicator Test Package (Biological Indicator- Type 5 Integrator), Triple Biological indicator Test Package (Biological Indicator, Type 5 Integrator and Inner PCD Type 6 Indicators) and Packaging of Disposable Medical Products

Certificate No. : IQM-TC-6666
Certificate Initial Issue Date : 17.01.2024
Certificate Issue Date : 17.01.2024
Certificate Expire Date : 16.01.2025

This certificate is valid for a period of three years from the date of initial publication if the IQM documentation rules are followed and the annual surveillance audits are completed successfully. The validity of the certificate will be made every year depends on surveillance control. The validity of the Certificate can be reviewed via www.iqm.com.tr



GENERAL MANAGER

