



Certificate Of Compliance

DÖRT-A TIP MALZEMELERİ SANAYİ İTH. İHR. TİC. LTD. ŞTİ.

BALIKHISAR MAHALLESİ, KÖY İÇİ SERPMELERİ, NO: 795/A, AKYURT, ANKARA, TÜRKİYE

Certex Certification confirms that the above-mentioned organization has evaluated the Medical Devices Management System and that it complies with the requirements of the relevant standard.

ISO 13485:2016

Scope,

Production, Design, Assembly and Packaging of Sterilization Reels (Flat, Gusset, Tyvek and Reinforced) and Pouches (Flat, Gusset, Tyvek, Self Sealing, Reinforced Flat, Reinforced Self Sealing, Gamma), Header Bag, Bowie-Dick Test Packages (200 Sheet, 400 Sheet, 200 Sheet Wrapped With Crepe Paper, 400 Sheet Wrapped With Crepe Paper, With Box, Wrapped With Crepe Paper & EWS) A4 Bowie-Dick, Mini 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)), Longtime 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, Label Gun, Steam and Ethylene Oxide Marker, Incubator, Steam and Ethylene Oxide Dot Sticker, Sterile Container Systems and Accessories, Container Label, Container Seal, Container Filter, Documentation Labels with Indicator (Steam, Ethylene Oxide, H2O2 (Plasma), Dry Heat), Instrument Protector, Reel Barcode Labels with Indicator, Washer Disinfectors, Washing Control Tests of Ultrasonic Devices and Surgical Instruments (Pro Test, Hemo Tests, Washer Test, Washer Test with Glass, PLS Cannula Control Test, Sonicontrol Test), Aluminum Sonicontrol Test and Aluminum Washer Test, Plastic Washer Test, Plastic Sonicontrol Test, Double Biological Indicator Test Package (Biological Indicator- Type 5 Integrator), Double Load Control Test Package (Type 5 integrator and Inner PCDIndicator), Triple Biological indicator Test Package (Biological Indicator, Type 5 Integrator and Inner PCD Type 6 Indicators) and Packaging, of Disposable Medical Products

This certificate is based on compliance with Certex Certification rules and annual surveillance audits are successfully completed, the date of the first publication valid for a period of three years. The validity of the certificate is subject to an annual depends on the surveillance audit. Certificate validity status It can be checked at www.certex.com.tr.

Certificate No : CER-TC-0040
Certificate Initial Issue Date : 13.01.2025
Certificate Issue Date : 13.01.2025
Certificate Validity Date : 12.01.2026

Certex Certification Training and Surveillance Services Ltd. Co.
İÇERENKÖY MAH ŞEHİT YILMAZ HID SOK. NO:5/A ATAŞEHİR / İSTANBUL
90 216 574 94 77 info@certex.com.tr / www.certex.com.tr



GENEL MÜDÜR
GENERAL MANAGER

DECLARATION OF CONFORMITY

MANUFACTURER: DÖRT-A TIP MALZEMELERİ SANAYİ İTHALAT İHRACAT TİCARET LİMİTED ŞİRKETİ

Address: Balıkhisar Mahallesi Köyiçi Serpmeleri No795A Akyurt, Ankara, Turkey

Products: Bowie Dick Test Pack, Indicator Strips (H2O2 Indicator Strip, Formaldehyde Indicator Strip, Ethylene Oxide Indicator Strip, Dry heat Indicator Strip, Type 4 Indicator Strip 4ASI, 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), Sterile Container System, Container Label, Container Seal, Container Filter, Documentation Labels with Indicator, Reel Barcode Labels with Indicator; Label Gun, Washer Disinfectors, Ultrasonic Devices and Washing Control Tests of Surgical Instruments (Pro Test, Hemo Tests, Washer Test, Cannula control Test, Sonicontrol Test.

Above described products complied with below norms.

DOCUMENT NO	TITLE	EDITION / DATE OF ISSUE
TS EN ISO 11140-1	Chemical Indicators	18.02.2015
TS EN ISO 11140-4	Bowie Dick Test Pack	31.01.2008
TS EN 11138-1	Biological Indicators	24.04.2017
TS EN 15883-1	Washing Machine Disinfectant Residue Test	30.10.2014

Additional information: The development, production and the distribution is supported with a Quality Management System according to the requirements of the ISO 9001:2015 and ISO 13485:2016. The Quality Management System is certificated through the notified body ROYALCERT (Certificate No: 108 / DOR09B and 108 / DOR13A)

If no changes made Declaration of Conformity will remain valid.

On 24th February, 2022 at Ankara, Turkey

Canan Öktem

General Manager