



# EC CERTIFICATE

## Full Quality Assurance System

### Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : Dört A Tıp Malzemeleri San. İth. İhr. Tic. Ltd. Şti.  
Company Address : Balıkhisar Mah. Köyiçi Serpmeleri No:795/A Akyurt ANKARA / TURKEY  
Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)  
Product :  
- Sterile/ Non-sterile Polypropylene Mesh - Class IIb  
- Sterile/ Non-sterile Esu Pencil - Class IIb  
- Sterile/ Non-sterile T Drain - Class IIa  
- Sterile/ Non-sterile PVC Straight Drain (normal- blue x-ray line) - Class IIa  
- Sterile/ Non-sterile Silicone Straight Drain (normal- blue x-ray line) - Class IIa  
- Sterile/ Non-sterile PVC Thorax Drain (blue x-ray line) - Class IIa  
- Sterile/ Non-sterile Silicone Thorax Drain (blue x-ray line) - Class IIa  
- Sterile/ Non-sterile Flat Drain (normal/ blue x-ray line) - Class IIa  
- Sterile/ Non-sterile PVC Redon Drain (blue x-ray line) - Class IIa  
- Sterile/ Non-sterile Silicone Redon Drain (blue x-ray line) - Class IIa  
- Sterile/ Non-sterile Channel Drain (normal/ blue x-ray line) ( Flat/ round ) - Class IIa  
- Sterile/ Non-sterile Drain Suction Set (Yanquer Set ) With vacuum / Without vacuum - Class IIa  
- Sterile/ Non-sterile Penrose Drain (blue x-ray line) - Class IIa  
- Sterile/ Non-sterile Silicone Hemovac Drain Set Single/ Double - Class IIa  
- Sterile/ Non-sterile PVC Hemovac Drain Set Single / Double - Class IIa  
- Sterile/ Non-sterile Esu Pencil Cleaner - Class Is  
- Sterile/ Non-sterile Aspiration Tube - Class Is  
- Sterile/ Non-sterile Passive Chest Drainage Bottle 2000ml - Class Is  
- Sterile/ Non-sterile Bomb Reservoir - Class Is  
- Sterile/ Non-sterile Aspiration Handle (Yanquer Handle) (With vacuum / Without vacuum) - Class IIa

GMDN : 44681, 60300, 35824, 11305, 11301, 35917, 44643  
Certificate Number : M.2016.106.7276  
Report Number : MD.3334-YB  
Initial Assessment Date : 31.07.2012  
Registration Date : 05.12.2016  
Recertification Assessment Date : 30.11.2020  
Reissue Date : 29.04.2021/02  
Revision Date /No : -  
Expiry Date : 27.05.2024



UDEM International Certification  
Auditing Training Centre Industry  
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned



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# SERTİFİKA

Sertifika No	: 00108/DÖR13A
Belgelendirme Tarihi	: 20.01.2010
Yeniden Belgelendirme Karar Tarihi	: 07.01.2022
Yayın Tarihi	: 11.01.2023
Geçerlilik Tarihi	: 19.01.2024
Revizyon Tarihi/No	: 31.12.2018 / 01

Royalcert, aşağıda bilgileri verilen kuruluşun yönetim sisteminin değerlendirildiğini ve ilgili standardın gereklerine uygun olduğunu onaylar.

## ISO 13485:2016

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

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

**Scope:** Sterilizasyon Rulosu ve Torbaları, Kendinden Yapışkanlı Sterilizasyon Zarfları, Bowie-Dick Testi Paketleri, İndikatör Kartları (H2O2 (Plasma), Formaldehit İndikatör Kartları, Etilen Oksit İndikatör Kartları, Kuru Hava İndikatör Kartları, Sınıf 4 İndikatör Kartları, Sınıf 5 İndikatör Kartları, Sınıf 6 İndikatör Kartları), Sınıf 5 İntegratör, Rapid Buhar Biyolojik İndikatörü, Uzun Süreli Buhar Biyolojik İndikatörü, Etilen Oksit Biyolojik İndikatörü, H2O2 (Plasma) Biyolojik İndikatörü, Helix Küme Testi, Pcd Küme Testi, Etilen Oksit Yük Kontrol Testi, Otoklav Bantları (Buhar, Etilen Oksit, Plasma, Formaldehite), Koter Kalemleri, Koter Zımparası, Wrap ve Krep Kağıtları, Vücut-Yara Atık Sıvıları için Drenaj Sistemleri (Kateterler, Toplama Şişeleri), Polypropylene Mesh, Steril Konteynir Sistemleri, Konteynir Etiketleri, Konteynir Kilidi, Konteynir Filtresi, İndikatörlü Dokümantasyon Etiketleri, İndikatörlü Rulo Barkod Etiketleri; Yıkayıcı Dezenfektörler, Ultrasonik Cihazlar Ve Cerrahi Aletlerin Yıkama Kontrol Testleri (Protest, Hemotest, Washertest, Cannulacontrol Test, Sonicontrol Test), İkili Biyolojik İndikatör Test Paketi (Biyolojik İndikatör - Type 5 Entegratör), İkili Yük Kontrol Test Paketi (Type 5 Entegratör ve PCD içi Type 6 İndikatör), Üçlü Biyolojik İndikatör Test Paketi (Biyolojik İndikatör, Type 5 Entegratör ve PCD içi Type 6 İndikatör), Üretimi, Tasarımı, Montajı, Paketlenmesi, Pazarlanması ve Satışı, Tek Kullanımlık Tıbbi Malzemelerin Paketlenmesi

Genel Müdür



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# CERTIFICATE

Certification No : 00108/DÖR13A  
Initial Certification Date : 20.01.2010  
Recertification Date : 07.01.2022  
Issue Date : 07.01.2022  
Expiration Date : 19.01.2024  
Revision Date / No : 31.12.2018 / 01

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 İTH. İHR. TİC. LTD. ŞTİ.**

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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