CERTIFICATE

Certification No	**: 00108/DÖR13A**
Initial Certification Date	**: 20.01.2010**
Recertification Date	**: 31.12.2018**
Issue Date	**: 22.01.2021**
Expiration Date	**: 19.01.2022**
Revision Date / No	**: 31.12.2018 / 01**

RoyalCert International Registrars, 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 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 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

ROYALCERT INTERNATIONAL REGISTRARS
ROYALCERT

RoyalCert

This certification was conducted in accordance with the relevant 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
This certification can be verified on TÜRKAK BDS no. and TBDS.turkak.org.tr

Digitally signed by Cojocaru Vera
Date: 2021.04.12 16:41:32 EEST
Reason: MoldSign Signature
Location: Moldova

RoyalCert Belgelendirme ve Gözetim A.Ş
Kar Plaza E Blok K:13 34752
Ataşehir, İstanbul
T:+90 216 688 09 10

CERTIFICATE

Certification No	**: 00108/DÖR09B**
Initial Certification Date	**: 20.01.2010**
Recertification Date	**: 31.12.2018**
Issue Date	**: 22.01.2021**
Expiration Date	**: 19.01.2022**
Revision Date / No	**: 31.12.2018 / 01**

RoyalCert International Registrars, 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 9001:2015

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 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

TÜRKAK
Kalite Yönetim Sistemi
TS EN ISO/IEC 17021-1
AB-0014-YS

TÜRKAK BDS NO
YS-CDDC-C45(

RoyalCert

This certification was conducted in accordance with the RoyalCert auditing and certification procedures and is subject to regular surveillance audits.
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RoyalCert Belgelendirme ve Gözetim A.Ş
Kar Plaza E Blok K:13 34752
Ataşehir, İstanbul
T:+90 216 688 09 10

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 Polypropylene Mesh - Class IIb
- Sterile Esu Pencil - Class IIb
- Sterile T Drain - Class IIa
- Sterile PVC Straight Drain (normal- blue x-ray line) - Class IIa
- Sterile Silicone Straight Drain (normal- blue x-ray line) - Class IIa
- Sterile PVC Thorax Drain (blue x-ray line) - Class IIa
- Sterile Silicone Thorax Drain (blue x-ray line) - Class IIa
- Sterile Flat Drain (normal/ blue x-ray line) - Class IIa
- Sterile PVC Redon Drain (blue x-ray line) - Class IIa
- Sterile Silicone Redon Drain (blue x-ay line) - Class IIa
- Sterile Channel Drain (normal/ blue x-ray line) (Flat/ round) - Class IIa
- Sterile Drain Suction Set (Yankuer Set) Vacuum/ Non-Vacuum - Class IIa
- Sterile Penrose Drain (blue x-ray line) - Class IIa
- Sterile Silicone Hemovac Drain Set Single/ Double - Class IIa
- Sterile PVC Hemovac Drain Set Single / Double - Class IIa
- Sterile Esu Pencil Cleaner - Class Is
- Sterile Aspiration Tube - Class Is
- Sterile Passive Chest Drainage Bottle 2000ml - Class Is
- Sterile Bomb Reservoir - Class Is

GMDN : 44681, 60300, 35118, 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 : 26.07.2017
Reissue Date : 24.10.2017/01
Revision Date /No : 09.06.2020/01
Expiry Date : 07.08.2022

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 applied 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 validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

TÜRK STANDARDLARI ENSTİTÜSÜ

TÜRK STANDARDLARINA UYGUNLUK BELGESİ

TURKISH STANDARDS INSTITUTION

CERTIFICATE OF CONFORMITY TO TURKISH STANDARDS

Markanın Tanımı — Description of the Mark

TSE veya/or  veya/or

BELGE NUMARASI *REFERENCE NUMBER OF LICENCE*	001867-TSE-01/02
BELGENİN İLK VERİLİŞ TARİHİ *DATE OF FIRST ISSUE OF LICENCE*	14.11.2012
BELGENİN SON GEÇERLİLİK TARİHİ *LICENCE VALID UNTIL*	08.05.2021
BELGE SAHİBİ KURULUŞUN ADI *NAME OF THE LICENCE HOLDER*	DÖRT A TIP MALZEMELERİ SANAYİ İTHALAT İHRACAT TİCARET LTD ŞTİ.
BELGE SAHİBİ KURULUŞUN ADRESİ *ADRESS OF THE LICENCE HOLDER*	BALIKHİSAR MAH. BALIKHİSAR KÖY İÇİ KM. EVL. NO:795 AKYURT ANKARA/TÜRKİYE
ÜRETİM YERİ ADI *NAME OF THE MANUFACTURING PLACE*	DÖRT-A TIP MALZEMELERİ SAN. İTH. İHR.TİC. LTD. ŞT.
ÜRETİM YERİ ADRESİ *ADRESS OF THE MANUFACTURING PLACE*	BALIKHİSAR MAHALLESİ KÖY İÇİ SERPMELERİ NO:795 AKYURT ANKARA / TÜRKİYE
İPTAL EDİLEN BELGE NUMARASI (Varsa) *INDICATION OF SUPERSEDED LICENCE (if any)*	001867-TSE-01/01
TESCİLLİ TİCARİ MARKASI *REGISTERED TRADE MARK*	4A DÖRT A TIP SANAYİ
İLGİLİ TÜRK STANDARDI *RELATED TURKISH STANDARD*	TS EN 868-5 / 28.01.2019

BELGE KAPSAMI
SCOPE OF LICENCE

Nihai olarak sterilize edilen tıbbi cihazlar için ambalajlama malzemeleri ;
Gözenekli malzemelerden ve plastik filmden yapılan kendinden kapatılabilir poşetler ve rulolar.

e-imzalı/e-signed

04.05.2020

Belgelendirme Merkezi Başkanı Adına
ÖZER ÖZGÖKÇE

KİMYA SEKTÖR MÜDÜRÜ

*Bu belge, belgelendirilen ürünün, üretim yerinin Enstitümüzün belirlediği şartları karşıladığını da gösterir.
*Bu belge, hiç bir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz.
*TSE KİMYA SEKTÖRÜ MÜDÜRLÜĞÜ * Adres: Necatibey Cad.No:112 06100 Bakanlıklar/ANKARA * Telefon: 3124166489* Faks: 3124166617
*TSE BELGELENDİRME MERKEZ BAŞKANLIĞI: Adres: Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA – Telefon: 0 312 416 64 81 / 416 64 27, Faks:0 312 416 68 17 E-posta :bmb@tse.org.tr , web : www.tse.org.tr