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

Digitally signed by Cojocaru Vera
Date: 2021.01.11 08:54:28 EET
Reason: MoldSign Signature
Location: Moldova

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

ROYALCERT INTERNATIONAL REGISTRARS

SERTİFİKA

Sertifika No	**: 00108/DÖR13A**
Belgelendirme Tarihi	**: 20.01.2010**
Yeniden Belgelendirme Karar Tarihi	**: 31.12.2018**
Yayın Tarihi	**: 11.01.2020**
Geçerlilik Tarihi	**: 19.01.2021**
Revizyon Tarihi/No	**: 31.12.2018 / 01**

RoyalCert Belgelendirme, aşağıda bilgileri verilen kuruluşun yönetim sisteminin yine aşağıda detayları verilen yönetim standardının gereklerine uygunluğunu değerlendirmiş olup, ilgili standart şartlarına uygun olduğunu onaylar.

ISO 13485:2016

DÖRT-A TIP MALZEMELERİ SAN. İTH. İHR. TİC. LTD. STİ.

Balıkhisar Mahallesi Köyiçi Serpmeleri No:795/A Akyurt / ANKARA, TÜRKİYE

Kapsam: *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, Vücüt-Yara Atık Sıvıları için Drenaj Sistemleri (Kateterler, Toplama Şişeleri), Polypropylene Mesh, Steril Konteynır Sistemleri, Konteynır Etiketi, Konteynır Kilidi, Konteynır 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 Indikatör - Class 5 Entegratör), İkili Yük Kontrol Test Paketi (Class 5 Entegratör ve PCD içi Class 6 İndikatör), Üçlü Biyolojik İndikatör Test Paketi (Biyolojik İndikatör, Class 5 Entegratör ve PCD İçi Class 6 İndikatör), Steril ve Non Steril Ağız Bakım Seti(Ağız Bakım Çubuğu, Gargara Solüsyonu, Jel) Üretimi, Tasarımı, Montajı, Paketlenmesi, Pazarlanması ve Satışı, Tek Kullanımlık Tıbbi Malzemelerin Paketlenmesi.*

Genel Müdür

ROYALCERT INTERNATIONAL REGISTRARS
ROYALCERT

RoyalCert

FSC

Bu sertifika, belgeli kuruluş gözetim denetimleri şartlarına ve RoyalCert'in prosedürlerine uyduğu sürece geçerlidir.
Orjinal belgede hologram etiket bulunur .Belgelendirme periyodu 3 yıldır.
Sertifikanın durumu www.royalcert.com adresinden ayrıca üzerinde kare kod bulunan sertifikaların geçerliliği de TÜRKAK BDS no. ile TBDS.turkak.org.tr üzerinden doğrulanabilir.

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

ROYALCERT INTERNATIONAL REGISTRARS

CERTIFICATE

Certification No	**: 00108/DÖR13A**
Initial Certification Date	**: 20.01.2010**
Recertification Date	**: 31.12.2018**
Issue Date	**: 11.01.2020**
Expiration Date	**: 19.01.2021**
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. STİ.

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, Class 4 Indicator Strip, Class 5 Indicator Strip, Class 6 Indicator Strip), Class 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- Class 5 Integrator), Double Load Control Test Package (Class 5 Integrator and Inner PCD Class 6 Indicator), Triple Biological Indicator Test Package (Biological Indicator, Class 5 Integrator and Inner PCD Class 6 Indicator) and Packaging,of Disposable Medical Products*

General Manager

ROYALCERT INTERNATIONAL REGISTRARS ROYALCERT

RoyalCert

FSC

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

RoyalCert International Registrars GmbH
Kölner Strasse 44, D-60327
Frankfurt am Main Germany
T: +49 698 609 25 69 | F: +49 691 729 73 00

CERTIFICAT DE CONFORMITATE

MOLDAC
REPUBLICA MOLDOVA
SM SR EN ISO/CEI 17065
OCpr-003

OC ICC

Nr. de înregistrare **OC ICC 13 C0006788-20**

Data emiterii 24 iulie 2020 **Valabil pînă** 24 iulie 2021

ORGANISMUL DE CERTIFICARE OCpr. - 003

ORGANISMUL DE CERTIFICARE produse din cadrul SC "Inspecţie-Certificare-Calitate" S.R.L.
MD 2032, mun. Chişinău, str. Sarmizegetusa, 92, tel./fax 022 50-70-75, www.certificare.md
Certificat de acreditare nr. OCpr - 003 valabil pînă la 28.11.2022.

PRIN PREZENTUL DOCUMENT SE CONFIRMĂ FAPTUL, CĂ PRODUSELE IDENTIFICATE ASTFEL:
DENUMIREA / DESCRIEREA

Codul NCM
3401

Şerveţele umede, inclusiv pentru copii, mărcile: "Freshmaker"®, "freshRuny"®, "NEMDIL"®.
Livrarea produselor conform contractului nr.13-12 din 14.03.2012 cu FULYA KOZMETIK Islak Mendil Imalat ve Pazarlama Ltd. Şti, Turcia.

SÎNT CONFORME CU CERINŢELE OBLIGATORII STABILITE ÎN :
SM GOST R 52354:2006 p.3.2, 3.3, 3.6.1 (tab.1, grupa Б-3), 3.8.1, 3.8.3, 3.8.8, 3.13, 3.14, 6;
RN SE nr.06.10.3.66 din 22.12.2004, anexa 3.

PRODUCĂTOR
FULYA KOZMETIK Islak Mendil Imalat ve Pazarlama Ltd. Şti, Turcia

Codul ţării
TR

SOLICITANT
F.P.C. "TEHELAN" S.R.L, str. Doina 199/1, mun. Chişinău, Republica Moldova

Codul IDNO
1002600028030

CERTIFICATUL ESTE ELIBERAT ÎN BAZA
Raportului a încercărilor de laborator nr. 4150 din 13.07.2020, eliberat de Centrul de Încercări de Laborator din cadrul Agenţiei Naţionale pentru Sănătate Publică, certificat de acreditare Nr. LÎ-044 valabil pînă la 16.02.2022, mun. Chişinău, str. Gh. Asachi, 67a; Raportului de identificare a produselor nr. M-8762-20 din 01.07.2020, Raportului de control tehnic al produselor supuse certificării nr. M-8762-20 din 01.07.2020 şi Raportului sumar asupra rezultatelor certificării produselor nr. M-8762-20 din 23.07.2020, eliberate de OC "ICC".

INFORMAŢIE SUPLIMENTARĂ:
Schema certificării produselor nr. 2. Evaluarea periodică se va efectua o dată pe an de OC "ICC" conform contractului de evaluare periodică nr.20.22.8762-EPPC din 24.07.2020. Certificatul este valabil doar în cazul asigurării cu informaţia în limba de stat a fiecărei unităţi de produs, conform legislaţiei în vigoare.

CONDUCĂTORUL ORGANISMULUI DE CERTIFICARE Neaga O.

SOCIETATEA COMERCIALĂ * S.R.L. INSPECŢIE-CERTIFICARE-CALITATE L.Ş * IDNO 1004600070859 * REPUBLICA MOLDOVA * mun. CHIŞINĂU

Seria A Nr. 0006788

În atenţia antreprenorilor şi organelor de control !
Copiile certificatelor se legalizează prin specimenul de ştampilă şi semnătura deţinătorului certificatului

Certificate

kiwa
Partner for progress

AT Sertifikası

Üretim Kalite Güvence Sistemi

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V

Sertifika Numarası: 1984-MDD-16-369

Aşağıda bahsi geçen kuruluşun üretim kalite güvence sistemine ait incelemesinin, tıbbi cihazlara dair 93/42/AT yönetmeliği Ek-V gereksinimlerine göre yapıldığını beyan ederiz. Üretim kalite güvence sisteminin yukarıda bahsi geçen yönetmeliğin ilgili koşullarına uygunluğunu tasdik ederiz.

Kuruluş:

HONNES SAĞLIK VE ENDÜSTRİYEL ÜRÜNLERİ ANONİM ŞİRKETİ

Cumhuriyet Mah. Karayel Sok. No: 14 Çayırova, Kocaeli, Türkiye

Ürünler: Steril Hazır Pansuman Örtü, Steril Kateter Sabitleme Bandı, Steril Göz Pedi, Steril Hemostatik Bası Bandı, Steril ve Non-Steril Hidrofil Gazlı Bez ve Gaz Kompres

Sertifika son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile tamamlanmasına tabidir. Detaylar için lütfen Kiwa Meyer'e başvurunuz.

Rapor No: M.4589.01
Son Geçerlilik Tarihi: 07 Şubat 2019

Kiwa Meyer Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği 93/42/AT altında bir onaylanmış kuruluş olup kimlik numarası 1984'tür.

08 Şubat 2016, İstanbul, Türkiye

Onaylanmış Kuruluş Başkanı

Kiwa Meyer Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Türkiye
Tel.: +90 216 593 25 75 , Faks: +90 216 593 25 74
Web: www.kiwa.com.tr , e-posta: posta@meyer.gen.tr

* Mühürsüz sertifikalar geçersizdir.

Certificate

HONNES SAĞLIK VE ENDÜSTRİYEL ÜRÜNLERİ A.Ş.

CUMHURİYET MH. KARAYEL SK. NO:14 ÇAYIROVA – KOCAELİ – TÜRKİYE

STERİL HAZIR PANSUMAN ÖRTÜ, STERİL KATATER SABİTLEME BANDI, STERİL GÖZ PEDİ, STERİL HEMOSTATİK BASI BANDI, STERİL VE NON-STERİL HİDROFİL GAZLI BEZ VE GAZ KOMPRES, NON-STERİL FLASTERLER VE İLK YARDIM BANTLARI TASARIMI, ÜRETİMİ VE SATIŞI

kapsamında

EN ISO 13485:2012

Tıbbi cihazlar - Kalite yönetim sistemleri - Mevzuat amaçları bakımından şartlar

"Standardın aşağıda verilen maddeleri hariç tutulmuştur"
"7.5.1.2.2" "7.5.1.2.3" "7.5.3.2.2"

Sertifika No	: M 10320
İlk Belgelendirme Tarihi	: 08 Şubat 2016
Sertifika Tarihi	: 08 Şubat 2016
Son Geçerlilik Tarihi	: 07 Şubat 2019

Genel Müdür

TÜRKAK
Tıbbi Cihazlar K. Y. S.
TS EN ISO/IEC 17021
AB-0006-YS

Kiwa Meyer Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cadde No. 15 Tepeören - Tuzla İstanbul – Türkiye
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: posta@meyer.gen.tr

Sertifikalar periyodik ara denetimlerin başarılı ile tamamlanması kaydıyla geçerlidir.
Detaylı bilgi için yukarıdaki numaralara başvurulabilir.

Sertifika Son Güncelleme Tarihi : 08 Şubat 2016- R 00

Certificate

HONNES SAĞLIK VE ENDÜSTRİYEL ÜRÜNLERİ A.Ş.

CUMHURİYET MH. KARAYEL SK. NO:14 ÇAYIROVA – KOCAELİ – TURKEY

with a scope of

STERILE WOUND DRESSING, IV CANULA FIXATION PLASTER, STERILE EYE PAD, STERILE HEMOSTATIC PREASURE PLASTER, STERILE & NON STERIL HIDROPHILE GAUZE AND SWAB, NON STERIL PLASTER AND FIRST AID STRIP DESIGN, PRODUCTION VE SALES

Medical devices - Quality management systems - Requirements for regulatory purposes

" Following elements of the standard are excluded "
"7.5.1.2.2" "7.5.1.2.3" "7.5.3.2.2"

EN ISO 13485:2012

Certificate No	: M 10320
Initial Certification Date	: 08 February 2016
Certification Date	: 08 February 2016
Expiration Date	: 07 February 2019

General Manager

Kiwa Meyer Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören - Tuzla İstanbul – Türkiye
Tel: + 90 216 593 25 75 Fax : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: posta@meyer.gen.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

Last Modified: 08 February 2016- R 00

TÜRKAK
Medical Device Q.M.S.
TS EN ISO/IEC 17021
AB-0006-YS

Certificate

HONNES SAĞLIK VE ENDÜSTRİYEL ÜRÜNLERİ A.Ş.

CUMHURİYET MH. KARAYEL SK. NO:14 ÇAYIROVA – KOCAELİ – TÜRKİYE

STERİL HAZIR PANSUMAN ÖRTÜ, STERİL KATATER SABİTLEME BANDI, STERİL GÖZ PEDİ, STERİL HEMOSTATİK BASI BANDI, STERİL VE NON-STERİL HİDROFİL GAZLI BEZ VE GAZ KOMPRES, NON-STERİL FLASTERLER VE İLK YARDIM BANTLARI TASARIMI, ÜRETİMİ VE SATIŞI

kapsamında

ISO 9001:2008

Uluslararası kalite sistem standardına uygun
bir kalite yönetim sistemi kurmuştur.

"Standardın aşağıda verilen maddeleri hariç tutulmuştur"
"Hariç tutma yoktur."

Sertifika No	: M 10319
İlk Belgelendirme Tarihi	: 08 Şubat 2016
Sertifika Tarihi	: 08 Şubat 2016
Son Geçerlilik Tarihi	: 14 Eylül 2018

Genel Müdür

Kiwa Meyer Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cadde No. 15 Tepeören - Tuzla İstanbul – Türkiye
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: posta@meyer.gen.tr

Sertifikalar periyodik ara denetimlerin başarılı ile tamamlanması kaydıyla geçerlidir.
Detaylı bilgi için yukarıdaki numaralara başvurulabilir.

Sertifika Son Güncelleme Tarihi : 08 Şubat 2016- R 00

TÜRKAK
Kalite Yönetim Sistemi
TS EN ISO/IEC 17021
AB-0006-YS

Certificate

HONNES SAĞLIK VE ENDÜSTRİYEL ÜRÜNLERİ A.Ş.

CUMHURİYET MH. KARAYEL SK. NO:14 ÇAYIROVA – KOCAELİ – TURKEY

with a scope of

STERILE WOUND DRESSING, IV CANULA FIXATION PLASTER, STERILE EYE PAD, STERILE HEMOSTATIC PREASURE PLASTER, STERILE & NON STERIL HIDROPHILE GAUZE AND SWAB, NON STERIL PLASTER AND FIRST AID STRIP DESIGN, PRODUCTION VE SALES

Has established a quality management system in accordance with international standard.

" Following elements of the standard are excluded "
" None "

ISO 9001:2008

Certificate No	: M 10319
Initial Certification Date	: 08 February 2016
Certification Date	: 08 February 2016
Expiration Date	: 14 September 2018

General Manager

Kiwa Meyer Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören - Tuzla İstanbul – Türkiye
Tel: + 90 216 593 25 75 Fax : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: posta@meyer.gen.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

Last Modified: 08 February 2016- R 00

TÜRKAK
Quality Management System
TS EN ISO/IEC 17021
AB-0006-YS

Certificate

EC Certificate

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-16-369

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

HONNES SAĞLIK VE ENDÜSTRİYEL ÜRÜNLERİ ANONİM ŞİRKETİ

Cumhuriyet Mah. Karayel Sok. No: 14 Çayırova, Kocaeli, Turkey

Products: Sterile Wound Dressing, Sterile IV Cannula Fixation Plaster, Sterile Eye Pad, Sterile Hemostatic Pressure Plaster, Sterile & Non Sterile Hydrophile Gauze And Swab

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa Meyer for details.

Report Number: M.4589.01
Expiry Date: 07 February 2019

Kiwa Meyer Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number : 1984

08 February 2016, Istanbul, Turkey

Head of Notified Body

Kiwa Meyer Certification Services Inc.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr e-mail: posta@meyer.gen.tr

* Certificates without seal are not valid.

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60139711 0001

Report No.: 17047213 009

Manufacturer:

SCW Medicath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60101918 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC 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, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-08-05

Date: 2019-08-05

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60139711 0001
Report No.: 17047213 009

Manufacturer:
SCW Medicath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
China

Products:

- Disposable Pressure Transducers
- Introducer Sets
- Guide Wires
- Angiographic Syringes
- Hemodialysis Catheterization Kits
- Patient-Controlled Analgesic Infusion Pumps
- Disposable Infusion Pumps
- Tracheostomy Tube Kits
- Percutaneous Nephrostomy Sets
- Ureteral Stent Sets
- Drainage Catheter Sets
- Transradial Introducer Sets
- Introducer Needles
- I.V Cannulas
- Cervical Ripening Balloon
- Postpartum Balloon

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-08-05

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60139711 0001
Report No.: 17047213 009

Manufacturer:
SCW Medicath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
China

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Dose-control Syringes
- Manifolds
- Stopcocks
- Balloon Inflation Devices
- Colored Piston Specialty Syringes
- Manifold Sets
- Infusion Sets with Needleless Adapters
- Connecting Tubings
- Pressure Bandages
- Hemostasis Valve Sets

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® III Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-08-05

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

SCW Medicath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Medical Devices
(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-09-18
Certificate Registration No.:	SX 60130880 0001
An audit was performed. Report No.:	17047213 005
This Certificate is valid until:	2021-07-08

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Certifizierungsstelle

Date 2018-09-18

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60130880 0001
Report No.: 17047213 005

Organization:
SCW Medicath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
China

Scope:

Products:

- Hemostasis Valve Sets
- Disposable Pressure Transducers
- Introducer Sets
- Guide Wires
- Connecting Tubings
- Angiographic Syringes
- Hemodialysis Catheterization Kits
- Patient-Controlled Analgesic Infusion Pumps
- Disposable Infusion Pumps
- Tracheostomy Tube Kits
- Percutaneous Nephrostomy Sets
- Ureteral Stent Sets
- Drainage Catheter Sets
- Transradial Introducer Sets
- Introducer Needles
- I.V Cannulas

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2018-09-18

X. Ren

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60130880 0001
Report No.: 17047213 005

Organization:
SCW Medicath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
China

Scope:

Products:

- Dose-control Syringes
- Manifolds
- Stopcocks
- Balloon Inflation Devices
- Colored Piston Specialty Syringes
- Manifold Sets
- Infusion Sets with Needleless Adapters
- Cervical Ripening Balloon
- Postpartum Balloon
- Pressure Bandages

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2018-09-18

X. Ren

EG-Zertifikat / *EC-Certificate*

gem. 93/42/EWG Anhang II ohne (4) / *acc. 93/42/EEC Annex II without (4)*

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Bıçakcılar Tıbbi Cihazlar Sanayi ve Ticaret A.Ş.
Osmangazi Mahallesi, Gazi Caddesi No: 21,
Esenyurt 34522 İstanbul
Türkiye

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Medizinische Einmalartikel und Absauggeräte
Disposable medical devices and devices for aspiration and vacuum extraction

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / *Reg.-No.* 04 232 980886
Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
bis / *until* 2021-09-16
Edition 7

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-07-04

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse III
Products of class III

Vent Catheter
Atrial Cannula
Vessel Cannula with / without check valve

Anmerkung: Für das Inverkehrbringen der in diesem Zertifikat genannten Klasse III Produkte wird eine gültige EG Auslegungsprüfbescheinigung gemäß MDD Anhang II (4) gefordert.
Note: *For the placing on the market of Class III devices covered by this certificate, a valid EC design-examination certificate according to MDD Annex II (4) is required.*

Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
Edition 12

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

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Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

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ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIb
Products of class IIb

Pressure Monitoring Set
Lekocyte Filter Set
Gamma Leukocyte Filter Set

Produkte der Klasse IIa
Products of class IIa

Thoracenthesis Set
Thoracic Catheter
Arterial Needle
Endotracheal Tube
Reinforced Endotracheal Tube
RAE Endotracheal Tube
Nasogastric Catheter
Stomach Catheter
Feeding Catheter
Manifold / Manifold Pressure
Three-Way Stopcock

Bericht Nr. / *Report No.* 3521 8285

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ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIa
Products of class IIa

Tourniquet Set
IV Cannulae
Suction Catheter
Microaggregate Filter Set (Blood Filter Set)
Soft Drain
Oxygen Catheter
Nasal Oxygen Cannulae
Oxygen Connecting Tube
Tracheostomy Tube
Extracorporeal PVC Tubing
Extracorporeal Tubing Set
Quick Prime Set
Cardioplegia Set
Wound Drainage Set
Infusion Pump Set
Yankauer Suction Set
Suction Connecting Tube
Surgical Braided Tape
Nelaton Catheter
Tiemann Catheter

Bericht Nr. / *Report No.* 3521 8285

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ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse IIa
Products of class IIa

Hydrophilic coated uretheral Catheter
IV Filter Set
Aspirators
Blood Transfusion Set
Rectal Catheter
Umbilical Catheter
Angiographic Kit
B-Soft Kit
Aortic Punch
Gas Sampling Line

Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
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ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Is (steril)
Products of class Is (sterile)

Urine Collection Bag
Pleural Drainage Set
Central Venous Pressure Set
Guedel Airway
Spigot
Extension Lines
Kapkon Connector
Straight Connector
Straight Luer Connector
Y Connector
Y Luer Connector
Stopper
Instopper
Umbilical Cord Clamp
T.U.R. Set / Arthroscopy set
Transfer Set
Intravenous Infusion Sets
Intravenous Infusion Sets / Flowmeter
Intravenous Infusion Sets / Burette

Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
Edition 12

M2.98

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

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ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Is (steril)
Products of class Is (sterile)

B-Safe
Intubation Stylet
Combi Stopper
Urimeter
Thoracic Drainage Set
Vaginal Specula
ENEMA Set
I.V. Infusion Set w/B-Flow Flow Regulator
Control Syringe
Meconium Aspiration Connector

Anmerkung: Für Produkte der Klasse I steril beschränkt sich das Zertifizierungsverfahren auf die Aspekte der Herstellungsschritte in Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität.
Note: *For products of class I sterile the certification process is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.*

Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
von / *from* 2018-09-17
Edition 12

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

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ANLAGE / *ANNEX*

Anlage 1, Blatt 7 von 7
Annex 1, page 7 of 7

Reg.-Nr. / *Reg. No.* 04 232 980886

Produkte der Klasse Im (mit Messfunktion)
Products of class Im (with measuring function)

Urimeter
C.V.P. Set
Pleural Drainage Set
Volumetric Exerciser (B-Spiro)
Infusion Set w/Burette
Thoracic Drainage Set

Anmerkung: Für Produkte der Klasse I mit Messfunktion beschränkt sich das Zertifizierungsverfahren auf die Herstellungsschritte in Zusammenhang mit der Konformität der Produkte mit den messtechnischen Anforderungen.
Note: *For products of class I with measuring functions the certification process is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.*

Bericht Nr. / *Report No.* 3521 8285

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Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

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ZLG-BS-236.10.16

ZERTIFIKAT / *Certificate*

DIN EN ISO / EN ISO 13485 : 2016

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Bıçakcılar Tıbbi Cihazlar Sanayi ve Ticaret A.Ş.

Osmangazi Mahallesi, Gazi Caddesi No: 21,
Esenyurt 34522 İstanbul
Türkiye

ein Qualitätsmanagementsystem nach der Norm DIN EN ISO 13485 : 2016 / EN ISO 13485 : 2016 - Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke - eingeführt hat und aufrechterhält.
Dieses Zertifikat stellt nicht den erforderlichen Nachweis zur Anbringung der CE-Kennzeichnung dar.

has established and maintains a quality management system that meets the requirements of DIN EN ISO 13485 : 2016 / EN ISO 13485 : 2016 - Medical devices - Quality management systems - Requirements for regulatory purposes.
This certificate is not an authorisation to affix the CE mark.

Geltungsbereich / *Scope*

Entwicklung, Herstellung, Sterilisation und Vertrieb von medizinischen Einmalartikeln.
Entwicklung, Herstellung und Vertrieb von medizinischen Geräten und deren Zubehör.

Design, Manufacturing, Sterilization and Distribution of Disposable Medical Devices.
Design, Manufacturing and Distribution of Medical Equipments and all their Accessories.

Reg.-Nr. / *Reg.-No.* 04 221 980886
Bericht Nr. / *Report No.* 3521 8284

Gültigkeit / *Validity*
von / *from* 2018-09-17
bis / *until* 2021-09-16
Edition 6

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-07-04

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

DAkkS Deutsche Akkreditierungsstelle D-ZM-12007-05-01