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/ies must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE marking is 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 this certificate can be checked through www.udem.com.tr.

Digitally signed by Cojocaru Vera
Date: 2022.01.14 04:37:57 EET
Reason: MoldSign Signature
Location: Moldova

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

CERTIFICATE

AT Sertifikası
Üretim Kalite Güvence Sistemi
Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V

Sertifika Numarası: 1984-MDD-20-649

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:

MEDCARE SAĞLIK ÜRÜNLERİ SANAYİ VE TİCARET ANONİM ŞİRKETİ

Fatih Mahallesi Çamlık Caddesi No:54 Gaziemir, İzmir, Türkiye

Ürünler: Steril Tek Kullanımlık Önlükler, Steril Tek Kullanımlık Örtüler, Steril Tek Kullanımlık Örtü Setleri, Steril Tek Kullanımlık Ekipman Kılıfları

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

Rapor No: M.5250.01

Son Geçerlilik Tarihi: 27 Mayıs 2024

Kiwa Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği Ek V'e uygun olarak steril şartların güvence altına alınması ve muhafaza edilmesi ile ilgili üretim yönleriyle sınırlı olan kalite sistemini denetlemiş ve kalite sisteminin Tıbbi Cihaz Yönetmeliği Ek V'deki uygulanabilir şartları karşıladığını tespit etmiştir.

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

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

08 Nisan 2020, İstanbul, Türkiye

Kiwa 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@kiwa.com

CERTIFICATE

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

Certificate Number: 1984-MDD-20-649

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:

MEDCARE SAĞLIK ÜRÜNLERİ SANAYİ VE TİCARET ANONİM ŞİRKETİ

Fatih Mahallesi Çamlık Caddesi No:54 Gaziemir, İzmir, Turkey

Products: Sterile Disposable Gowns, Sterile Disposable Drapes, Sterile Disposable Drape Packs, Sterile Disposable Equipment Covers

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

Report Number: M.5250.01

Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions in accordance with MDD Annex V and found that the quality system meets the applicable requirements in MDD Annex V.

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

08 April 2020, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
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@kiwa.com

TÜV NORD

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.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-16
bis / *until* 2023-09-16
Edition 8

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2020-04-16

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 IIb
Products of class IIb

Pressure Monitoring Set
Leukocyte 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.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2020-04-20

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*

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www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

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

Produkte der Klasse IIa
Products of class IIa

Tourniquet Set
IV Cannula
Suction Catheter
Microaggregate Filter Set (Blood Filter Set)
Soft Drain
Oxygen Catheter
Nasal Oxygen Cannula
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.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

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www.zlg.de
ZLG-BS-236.10.16

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
External Drainage Set
Vent Catheter
Vessel Cannula

Bericht Nr. / *Report No.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2020-04-20

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*

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www.zlg.de
ZLG-BS-236.10.16

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.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

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www.zlg.de
ZLG-BS-236.10.16

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.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2020-04-20

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*

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ZLG-BS-236.10.16

ANLAGE / *ANNEX*

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.* 3524 7139
3526 6208
3526 6290

Gültigkeit / *Validity*
von / *from* 2020-04-20
Edition 15

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2020-04-20

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
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www.zlg.de
ZLG-BS-236.10.16

EC Certificate

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

Registration No.: HD 60144232 0001

Report No.: 17047213 010

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

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60139711 0001

Expiry Date: 2024-05-26

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: 2020-05-26

Date: 2020-05-26

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 60144232 0001
Report No.: 17047213 010

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

Date: 2020-05-26

Fuxiu Sheng

TÜVRheinland®

Doc. 2/2, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60144232 0001
Report No.: 17047213 010

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

Products:

- Locking Drainage Catheters
- Percutaneous Access Sets
- ERCP Guidewires
- Manifolds
- Stopcocks
- Manifold Sets
- Connecting Tubings

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Dose-control Syringes
- Balloon Inflation Devices
- Colored Piston Specialty Syringes
- Infusion Sets with Needleless Adapters
- Pressure Bandages
- Hemostasis Valve Sets
- Injection Caps

Notified Body

Fuxiu Sheng

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-05-26

CERTIFICATE

AT Sertifikası

Üretim Kalite Güvence Sistemi

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V

Sertifika Numarası: 1984-MDD-20-682

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:

Medbar Tıbbi Malzemeler Turizm San. Ve Tic. A.Ş.

Fatih Mah. 1142 Sokak Sarnıç No:35 Gaziemir - İzmir - Türkiye

Ürünler: Damla Ayar Seti, Uzatma Hattı, Karman Kanül ve Karman Kanül Enjektör, Artroskopi Seti, Solunum Fonksiyon Test Cihazı Filtreli Ağızlık, Cilt İşaretleme Seti, Mukus Toplama Kabı, Valfli İdrar Torbası, Valfli Kusmuk Torbası, Cerrahi Kılıflar ve Örtüler, Endoskopi Ağızlığı, Smear Fırçaları, Amniyotik Pouch Açacağı, Göbek Klempi, Steril Luer Konnektör Kapak, Arter Kanül, Jinekolojik Toplayıcı, Y-Tipi Fototerapi Göz Bandı

Ürünler, sertifikanın bir parçası olan ekte tanımlanmış olup, ek bir sayfadan oluşmaktadır. Sertifika son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile tamamlanmasına tabidir. Detaylar için lütfen Kiwa Belgelendirme Hizmetleri'ne başvurunuz.

Rapor No:	M.5746.03
İlk Yayım Tarihi:	13 Temmuz 2020
Son Yayım Tarihi:	11 Mayıs 2021
Revizyon Numarası:	01
Son Geçerlilik Tarihi:	27 Mayıs 2024

Kiwa Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği Ek V'e uygun olarak metrolojik şartlara sahip cihazların uygunluğu ile ilgili üretim yönleri ve steril şartların güvence altına alınması ve muhafaza edilmesi ile ilgili üretim yönleriyle ile sınırlı olan kalite sistemini denetlemiş ve kalite sisteminin Tıbbi Cihaz Yönetmeliği Ek V'deki uygulanabilir şartları karşıladığını tespit etmiştir.

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

11 Mayıs 2021, İstanbul, Türkiye

Kiwa 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@kiwa.com.tr

CERTIFICATE

AT Sertifikası Eki:

Üretim Kalite Güvence Sistemi
Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V
Sertifika No: 1984-MDD-20-682, Revizyon Numarası: 01

İlgili tıbbi cihazlar;

Ürün Adı	Tipleri
Damla Ayar Seti	Damla Ayar Seti (Uzun, Döner Luer Lock, Y Portsuz, İğne Girişsiz)
	Silindirik Damla Ayar Seti (Uzun, Döner Luer Lock, Y Portsuz, İğne Girişsiz)
Uzatma Hattı	Uzatma Hattı (30cm- 50cm- 60cm- 75cm- 90cm- 100cm- 120cm- 150cm)
	Basınca Dayanıklı Uzatma Hattı (30cm- 50cm- 60cm- 75cm- 90cm- 100cm- 120cm- 150cm)
Karman Kanül ve Karman Kanül Enjektör	Karman Kanül (No: 3, 4, 5, 6, 7, 8, 9, 10,12)
	Tek Valfli Manuel Vakum Aspiratörü Set, Çift Valfli Manuel Vakum Aspiratörü Set, Tek Valfli Manuel Vakum Aspiratörü, Çift Valfli Manuel Vakum Aspiratörü
	Non Steril Tek Valfli Manuel Vakum Aspiratörü, Non Steril Çift Valfli Manuel Vakum Aspiratörü
Artroskopi Seti	Y-Tur Seti, Y-Tur Seti Puarlı
Solunum Fonksiyon Test Cihazı Filtreli Ağızlık	Küçük (26mm, 30mm, 33mm)
	Küçük Mandallı (26mm, 30mm, 33mm)
	Büyük (30mm, 33mm)
	Büyük Mandallı (30mm, 33mm)
Cilt İşaretleme Seti	Cilt İşaretleme Seti, İnce Uçlu Cilt İşaretleme Seti
Mukus Toplama Kabı	Mukus Toplama Kabı (15ml, 25ml, 40ml, 100ml)
	Mukus Toplama Kabı Hortumlu (40ml)
Valfli İdrar Torbası	Beyaz, Musluklu
Valfli Kusmuk Torbası	Şeffaf, Beyaz
Cerrahi Kılıflar ve Örtüler	Mikroskop Kılıfı, Kamera Kılıfı, Kartonlu Kamera Kılıfı, Teleskobik Kamera Kılıfı, Çemberli Kamera Kılıfı, Akordeon Katlı Kamera Kılıfı, Prob Kılıfı, Endoskopi Torbası, Skopi Kılıfı, C Kollu Skopi Kılıfı, Floroskopi Kılıfı, Ameliyat Tavan Lambası El Tutamaç Kılıfı
Endoskopi Ağızlığı	-
Smear Fırçaları	Fırça, Spatula
Amniyotik Pouch Açacağı	-
Göbek Klempi	-
Steril Luer Konnektör Kapak	-
Arter Kanül	18G, 20G, 22G
Jinekolojik Toplayıcı	Jinekolojik Toplayıcı, Jinekolojik Toplayıcı Enjektörlü
Y-Tipi Fototerapi Göz Bandı	Küçük, Orta, Büyük

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

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

11 Mayıs 2021, İstanbul, Türkiye

Kiwa 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@kiwa.com.tr

4a medical®
producing health for the world
Dört-A Tıp Malzemeleri
Sanayi İth. İhr. Tic. Ltd. Şti.
ADRES : Balıkhisar Mah.Köyiçi Serpmeleri No: 795 / A
Akyurt - ANKARA / TÜRKİYE
TEL : 0312.363 50 52-53
FAX : 0312.363 52 10
WEB : http://www.4amedical.com
E-MAİL : ankara@4amedical.com

DECLARATION OF CONFORMITY

In accordance with ISO / IEC

No 01 / 2015

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

Address: Balıkhisar Mahallesi Köyiçi Serpmeleri No795A Akyurt Ankara Turkey

Products: Sterilization Reels and Pouches (Flat, Gusset, Tyvek), Self Adhesive Sterilization Pouches, Bowie & Dick Test Pack 4ABD, Indicator Strips (H2O2 Indicator Strip, Formaldehyde Indicator Strip, Ethylene Oxide Indicator Strip, Dry heat Indicator Strip, Class 4 Indicator Card 4ASI, Class 5 Indicator Strip, Class 6 Indicator Strip, Class 6 Steam Indicator 3,5 minutes 4A6SI), Class 5 Integrator, Registration Card, Longtime Steam Biological Indicator, Longtime Ethylene Oxide Biological Indicator, Longtime H2O2 (Plasma) Biological Indicator, Helix Group Tests, PCD Group Tests, Ethylene Oxide load control test, Tapes (Steam, Ethylene Oxide, Plasma, Formaldehyde), Wrap and Crepe Paper Sheets, 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)), Double Biological Indicator Test Package (Biological Indicator- Class 5 Integrator), Biological Test Package, 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)

Above described products complied with below norms.

DOCUMENT NO	TITLE	EDITION / DATE OF ISSUE
93/42/EEC	Council Directive 93 / 42 / EEC Concerning Medical Devices	07.06.2011
TS EN 868-5	Material Packaging	27.12.2012
TS EN ISO 11140-1	Chemical Indicators	18.02.2015
TSE EN 868-9	Material Packaging	19.01.2010
TS EN ISO 11140-4	Bowie Dick Test Pack	31.01.2008
TS EN 11138-1	Biological Indicators	29.04.2008
TS EN 15883-1	Washing Machine Disinfector 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) as proof of the conformity of the products with the requirements of the Council Directive 93/42/EEC concerning Medical devices were considered in class 1 non sterilized products.

Declaration of Conformity is valid for 1 year.

Ankara Turkey 20.01.2021

Canan Öktem

General Manager

CERTIFICATE

Production Quality Assurance

Medical Devices Directive 93/42/EEC Annex V

Company Name	: Honnes Sağlık ve Endüstriyel Ürünleri A.Ş.
Company Address	: Cumhuriyet Mah. Karayel Sokak No:14 Çayırova KOCAELI / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex V
Product	: Sterile Ready To Use Wound Dressing (Nonwoven Polyurethane) - Class I Sterile Eye Pad - Class Is Sterile Haemostatic Pressure Band - Class Is Steril Catherer Fixation Band - Class Is - Nonwoven, Transparent - Polyurethane Nonwoven With Pad - Transparent With Pad - Polyurethane With Pad
GMDN	: 34864, 11661
Certificate Number	: M.2018.106.9658
Report Number	: MD.3508.YB
Initial Assessment Date	: 19.01.2016
Registration Date	: 10.05.2018
Recertification Assessment Date	: 05.12.2018
Reissue Date / No	: 27.02.2019/01
Revision Date /No	: -
Expiry Date	: 07.02.2024

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

UDEM hereby declares that the requirements of Annex V 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 audits, defined by Annex V, section 4 of the aforementioned directive. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev,ce 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 company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com. tr.

CE 2292 UDEM

Addrres: 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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2095157-1

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

Scope: Design and Development, Manufacture and Distribution of 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, Manifolds, Stopcocks, Manifold Sets, Connecting Tubings, Dose-control Syringes, Balloon Inflation Devices, Colored Piston Specialty Syringes, Infusion Sets with Needleless Adapters, Pressure Bandages, Hemostasis Valve Sets, Locking Drainage Catheters, Percutaneous Access Sets, ERCP Guidewires, Injection Caps

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10918574-100
Effective date: 2021-07-09
Expiry date: 2024-07-08
Issue date: 2021-07-05

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

CERTIFICATE

MEDBAR TIBBİ MALZEMELER TURİZM SANAYİ VE TİCARET ANONİM ŞİRKETİ

FATİH MAH. 1142 SOK. NO: 35 SARNIÇ GAZİEMİR - İZMİR - TÜRKİYE

CERRAHİ KILIF ÜRÜNLERİ, DAMLA AYAR SETİ ÜRÜNLERİ, KARMAN KANÜL ÜRÜNLERİ, ENDOSKOPİ AĞIZLIĞI, MUKUS TOPLAMA KABI ÜRÜNLERİ, İDRAR TOPLAMA ÜRÜNLERİ, ARTROSKOPİ SETİ ÜRÜNLERİ, KUSMUK TORBASI ÜRÜNLERİ, CERRAHİ TIRNAK FIRÇALARI, FİLTRELİ AĞIZLIK ÜRÜNLERİ, SMEAR FIRÇALARI, POUCH AÇACAĞI, PARAKON TÜP, Y-TİPİ FOTOTERAPİ GÖZ BANDI ÜRÜNLERİ, ARTER KANÜL, CİLT İŞARETLEME SETİ, GÖBEK KLEMPİ, JİNEKOLOJİK TOPLAYICI ÜRÜNLERİ, UZATMA HATTI, STERİL LUER KONNEKTÖR KAPAK, YOĞUN BAKIM ÜRÜNLERİNİN ÜRETİMİ, PAKETLENMESİ, STERİLİZASYONU, DEPOLANMASI, DAĞITIMI VE EN ISO 11135 STANDARDINA UYGUN ETİLEN OKSİT STERİLİZASYON HİZMETLERİ

kapsamında

EN ISO 13485:2016

Uluslararası Tıbbi Cihazlar Kalite Yönetim Sistemi Standardına uygun bir yönetim sistemi kurmuştur.

"Standardın aşağıda verilen maddeleri hariç tutulmuştur"
"7.5.3" "7.5.4" "7.5.9.2"

Sertifika No	: M 11326
İlk Belgelendirme Tarihi	: 03 Ekim 2019
Sertifika Tarihi	: 03 Ekim 2019
Son Geçerlilik Tarihi	: 02 Ekim 2022

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cadde No: 15 Tepeören Tuzla
İstanbul / Türkiye

Tel: + 90 216 593 25 75
Faks: + 90 216 593 25 74
info@kiwa.com.tr
www.kiwa.com.tr

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

Genel Müdür

TÜRKAK BDS NO
YS-16BC-C2DD

Sertifika Son Güncelleme Tarihi : 11 Mayıs 2021 - R 01

SERTİFİKA • CERTIFICATE • ASCERT • ZERTIFIKAT • CERTIFICAT

ASCERT Certification

CERTIFICATE

This certificate is granted to the organization,

APEX TEKNIK TEKSTIL VE SAGLIK URUNLERI SANAYI TICARET ANONIM SIRKETI

Head Office: Acidereosb Mahallesi Ordu Caddesi No:23 Saricam, Adana, TURKEY
Istanbul Branch: Oruc Reis Mahallesi Barbaros Caddesi Giyimkent Sitesi 16. Sokak No:102-104 Esenler, Istanbul, TURKEY

Production and Sales of Nonwoven, Single Use Medical Consumables (Mask, Caps, Shoe Cover, Sleeve Cover, Coverall, Gown, Sheet, Drape, Surgical Sets and Personal Protective Equipments etc.)

according to the scope,

ISO 13485:2016

to certify that quality management system for medical devices in accordance with standard's clauses is established and being implemented.

Date of first issue	:	26.01.2021
Date of issue	:	26.01.2021
Certificate period	:	3 years
Reissue date	:	25.01.2022
Certificate No	:	TH.2021.1225

SERTİFİKA • CERTIFICATE • ASCERT • ZERTIFIKAT • CERTIFICAT

REGISTERED ISO 13485

Best Quality Services
System Certificate Approved

BQS BELGELENDIRME VE EGITIM HIZMETLERI LIMITED SIRKETI
Mahfesigmaz Mahallesi 79159 Sokak No:3/1 Merve Apartmani B Blok Daire:2 Cukurova, Adana, TURKEY
Tel: +90 322 234 81 22 Fax: +90 322 232 81 22 e-mail: info@ascert.com.tr

TÜRKAK BDS NO
YS-B48D-D48A

TÜRKAK
Kalite Yönetim Sistemi
TS EN ISO/IEC 17021-1
AB-0055-YS

CERTIFICATE

ÇİFTÇİLER BİRLİK KAĞITÇILIK ANONİM ŞİRKETİ - SAKARYA ŞUBESİ

3. Organize Sanayi Bölgesi, 10. Yol, No:79, Söğütlü, Sakarya, TÜRKİYE

i.Yatak Koruyucu Örtü, Hasta Bezi, Emici Külot/Külotlu Hasta Bezi, Bebek Bezi, Alt Değiştirme Örtüsü,Köpek Alıştırma Pedi, Islak Havlu, Vücut Temizleme Havlusu, Perine Temizleme Havlusu, Antibakteriyel Islak Havlu, Islak Tuvalet Kağıdı, Muayene Masa Örtüsü, Yüzey Temizleme Havlusu-Mendili, Tuvalet Kağıdı, Havlu Kağıt, Peçete, Dispenser Peçete, Dispenser Havlu, Hareketli Havlu, İçten Çekmeli Tuvalet Kağıdı, İçten Çekmeli Havlu, Hayvan Temizleme Mendili Üretimi ve Satışı

ii.Klozet Kapak Örtüsü, Yara ve Cilt Temizleme Havlusu, Hasta Lifi, Vücut Yıkama Kesesi, Saç Yıkama Bonesi, Cerrahi Yüz Maskesi, Streç Film, Aluminyum Folyo, Buzdolabı Poşeti, Buz Torbası, Yanmaz Fırın Poşeti, Pişirme Kağıdı, Pasta Altı Kapsülü, Muffin Kalıp, Paslanmaz Çelik Çatal - Kaşık - Maşa - Çay Tabağı, Metal Süzgeç, Metal Fındık - Ceviz Kıracağı, Temizlik Bezi, Bulaşık Süngeri, Ovma Teli, Bulaşık Eldiveni, Arabalı Gırgır, Yırtılmayan Kağıt Havlu, Çöp Poşeti, Çamaşır İpi- Mandalı, Latex Eldiven, Lavabo Açıcı, WC Matik, Ayakkabı Süngeri, Pamuklu Çubuk, Banyo Lifi, Mum, Plastik Bardak- Tabak - Çatal - Kaşık - Bıçak - Karıştırıcı - Kase - Pipet, Karton Bardak - Tabak, Köpük Bardak - Tabak - Set, Aluminyum Kap, Kürdan, Ahşap Çöp Şiş - Adana Şiş - Karıştırıcı - Maşa - Kaşık - Spatula - Havan - Çatal - Merdane - Kesme Panosu - Demet Çıra, Temizlik Fırçası - Sapı, Plastik Camsil - Çekçek - Askı - Faraş - Tuvalet Kağıtlığı - Maşrapa - Sabunluk - Huni - Rende - Limon Sıkacağı - Badya, Sebze Meyve Soyacağı, Hamur Kesici, Sürahi, Vantuz Pompa, Krema Pompası, Kurabiye Kalıbı, Plastik Matara, Mangal Kömürü, Yelpaze, Izgara Teli, Mangal, Tutuşturucu Jel Paketlenmesi ve Satışı

TCS Belgelendirme tarafından denetlenmiş ve uygulamakta olduğu Kalite Yönetim Sisteminin

ISO 9001:2015

standardına yukarıdaki kapsamda uymakta olduğu gözlenmiştir.

Sertifika No: QM-00 90 200161-TR

Sertifika İlk Yayın Tarihi 09.09.2020

Sertifika Son Basım Tarihi 09.09.2021

Mevcut Belgelendirmenin Geçerlilik Periyodu 09.09.2020 - 09.09.2023

SERTİFİKA GEÇERLİLİK TARİHİ : 09.09.2022

INSPECTION TCS SYSTEM DEPARTMENT PRODUCT TRAINING

ONAY

Barbaros Mah. Halk Cad. Kent Sokak No: 10 Ataşehir / İSTANBUL
T: 0216 573 55 53 F: 0216 573 88 01 info@tcscert.com www.tcscert.com

CERTIFICATE

ÇİFTÇİLER BİRLİK KAĞITÇILIK ANONİM ŞİRKETİ - SAKARYA ŞUBESİ

3. Organize Sanayi Bölgesi,10. Yol, No:79, Söğütlü, Sakarya, TÜRKİYE

i.Yatak Koruyucu Örtü, Hasta Bezi, Emici Külot/Külotlu Hasta Bezi, Bebek Bezi, Alt Değiştirme Örtüsü,Köpek Alıştırma Pedi, Islak Havlu, Vücut Temizleme Havlusu, Perine Temizleme Havlusu, Antibakteriyel Islak Havlu, Islak Tuvalet Kağıdı, Muayene Masa Örtüsü, Yüzey Temizleme Havlusu-Mendili, Tuvalet Kağıdı, Havlu Kağıt, Peçete, Dispenser Peçete, Dispenser Havlu, Hareketli Havlu, İçten Çekmeli Tuvalet Kağıdı, İçten Çekmeli Havlu, Hayvan Temizleme Mendili Üretimi ve Satışı

ii.Klozet Kapak Örtüsü, Yara ve Cilt Temizleme Havlusu, Hasta Lifi, Vücut Yıkama Kesesi, Saç Yıkama Bonesi, Cerrahi Yüz Maskesi, Streç Film, Aluminyum Folyo, Buzdolabı Poşeti, Buz Torbası, Yanmaz Fırın Poşeti, Pişirme Kağıdı, Pasta Altı Kapsülü, Muffin Kalıp, Paslanmaz Çelik Çatal - Kaşık - Maşa - Çay Tabağı, Metal Süzgeç, Metal Fındık - Ceviz Kıracağı, Temizlik Bezi, Bulaşık Süngeri, Ovma Teli, Bulaşık Eldiveni, Arabalı Gırgır, Yırtılmayan Kağıt Havlu, Çöp Poşeti, Çamaşır İpi- Mandalı, Latex Eldiven, Lavabo Açıcı, WC Matik, Ayakkabı Süngeri, Pamuklu Çubuk, Banyo Lifi, Mum, Plastik Bardak- Tabak - Çatal - Kaşık - Bıçak - Karıştırıcı - Kase - Pipet, Karton Bardak - Tabak, Köpük Bardak - Tabak - Set, Aluminyum Kap, Kürdan, Ahşap Çöp Şiş - Adana Şiş - Karıştırıcı - Maşa - Kaşık - Spatula - Havan - Çatal - Merdane - Kesme Panosu - Demet Çıra, Temizlik Fırçası - Sapı, Plastik Camsil - Çekçek - Askı - Faraş - Tuvalet Kağıtlığı - Maşrapa - Sabunluk - Huni - Rende - Limon Sıkacağı - Badya, Sebze Meyve Soyacağı, Hamur Kesici, Sürahi, Vantuz Pompa, Krema Pompası, Kurabiye Kalıbı, Plastik Matara, Mangal Kömürü, Yelpaze, Izgara Teli, Mangal, Tutuşturucu Jel Paketlenmesi ve Satışı

TCS Belgelendirme tarafından denetlenmiş ve uygulamakta olduğu Medikal Cihaz Yönetim Sisteminin

ISO 13485:2016

standardına yukarıdaki kapsamda uymakta olduğu gözlenmiştir.

Sertifika No: MDM-00 90 200161-TR

Sertifika İlk Yayın Tarihi 09.09.2020

Sertifika Son Basım Tarihi 09.09.2021

Mevcut Belgelendirmenin Geçerlilik Periyodu 09.09.2020 - 09.09.2023

SERTİFİKA GEÇERLİLİK TARİHİ : 09.09.2022

INSPECTION PRODUCT TCS SYSTEM DEPARTMENT TRAINING SYSTEM

ONAY

Barbaros Mah. Halk Cad. Kent Sokak No: 10 Ataşehir / İSTANBUL
T: 0216 573 55 53 F: 0216 573 88 01 info@tcscert.com www.tcscert.com

CERTIFICATE

ÇİFTÇİLER BİRLİK KAĞITÇILIK ANONİM ŞİRKETİ - SAKARYA ŞUBESİ

3. Organize Sanayi Bölgesi, 10. Yol, No:79, Söğütlü, Sakarya, TÜRKİYE

i.Yatak Koruyucu Örtü, Hasta Bezi, Emici Külot/Külotlu Hasta Bezi, Bebek Bezi, Alt Değiştirme Örtüsü,Köpek Alıştırma Pedi, Islak Havlu, Vücut Temizleme Havlusu, Perine Temizleme Havlusu, Antibakteriyel Islak Havlu, Islak Tuvalet Kağıdı, Muayene Masa Örtüsü, Yüzey Temizleme Havlusu-Mendili, Tuvalet Kağıdı, Havlu Kağıt, Peçete, Dispenser Peçete, Dispenser Havlu, Hareketli Havlu, İçten Çekmeli Tuvalet Kağıdı, İçten Çekmeli Havlu, Hayvan Temizleme Mendili Üretimi ve Satışı

ii.Klozet Kapak Örtüsü, Yara ve Cilt Temizleme Havlusu, Hasta Lifi, Vücut Yıkama Kesesi, Saç Yıkama Bonesi, Cerrahi Yüz Maskesi, Streç Film, Aluminyum Folyo, Buzdolabı Poşeti, Buz Torbası, Yanmaz Fırın Poşeti, Pişirme Kağıdı, Pasta Altı Kapsülü, Muffin Kalıp, Paslanmaz Çelik Çatal - Kaşık - Maşa - Çay Tabağı, Metal Süzgeç, Metal Fındık - Ceviz Kıracağı, Temizlik Bezi, Bulaşık Süngeri, Ovma Teli, Bulaşık Eldiveni, Arabalı Gırgır, Yırtılmayan Kağıt Havlu, Çöp Poşeti, Çamaşır İpi- Mandalı, Latex Eldiven, Lavabo Açıcı, WC Matik, Ayakkabı Süngeri, Pamuklu Çubuk, Banyo Lifi, Mum, Plastik Bardak- Tabak - Çatal - Kaşık - Bıçak - Karıştırıcı - Kase - Pipet, Karton Bardak - Tabak, Köpük Bardak - Tabak - Set, Aluminyum Kap, Kürdan, Ahşap Çöp Şiş - Adana Şiş - Karıştırıcı - Maşa - Kaşık - Spatula - Havan - Çatal - Merdane - Kesme Panosu - Demet Çıra, Temizlik Fırçası - Sapı, Plastik Camsil - Çekçek - Askı - Faraş - Tuvalet Kağıtlığı - Maşrapa - Sabunluk - Huni - Rende - Limon Sıkacağı - Badya, Sebze Meyve Soyacağı, Hamur Kesici, Sürahi, Vantuz Pompa, Krema Pompası, Kurabiye Kalıbı, Plastik Matara, Mangal Kömürü, Yelpaze, Izgara Teli, Mangal, Tutuşturucu Jel Paketlenmesi ve Satışı

TCS Belgelendirme tarafından denetlenmiş ve uygulamakta olduğu İyi Üretim Uygulamaları

ISO 22716:2007 (GMP)

standardına yukarıdaki kapsamda uymakta olduğu gözlenmiştir.

Sertifika No: GMP-00 90 200161-TR

Sertifika İlk Yayın Tarihi 09.09.2020

Sertifika Son Basım Tarihi 09.09.2021

Mevcut Belgelendirmenin Geçerlilik Periyodu 09.09.2020 - 09.09.2023

SERTİFİKA GEÇERLİLİK TARİHİ : 09.09.2022

ONAY

Barbaros Mah. Halk Cad. Kent Sokak No: 10 Ataşehir / İSTANBUL
T: 0216 573 55 53 F: 0216 573 88 01 info@tcscert.com www.tcscert.com

TÜRKAK BDS NO
YS-B48D-D48A

CERTIFICATE

ÇİFTÇİLER BİRLİK KAĞITÇILIK ANONİM ŞİRKETİ - SAKARYA BRANCH

3. Organize Sanayi Bölgesi, 10. Yol, No:79, Söğütlü, Sakarya, TÜRKİYE

i. Underpad, Adult Diaper, Absorbent Panty/ Pull up Adult Pants, Baby Diaper, Baby Changing Mat, Dog Training Pad Wet Towel, Body Cleaning Towel, Perineum Cleaning Towel, Antibacterial Wet Towel, Wet Toilet Paper, Examination Table Cover, Surface Cleaning Towel -Tissues, Toilet Paper, Towel Paper, Napkin, Dispenser Napkin, Dispenser Towel, Emotion Towel, Centerfeed Towel, Centerfeed Toilet Paper,Pet Cleaning Wipes Production and Sales

ii.Toilet Seat Cover, Wound and Skin Cleaning Towel, Patient Washcloth, Body Washing Bag, Hair Wash Cap, Surgical Face Mask, Cling Film, Aluminum Foil, Refrigerator Bag, Ice Bag, Fireproof Baking Bag, Baking Paper, Under-Cake Capsule, Muffin Mold, Stainless Steel Cutlery - Spoon - Tongs - Tea Plate, Metal Strainer, Metal Nuts - Walnut Crusher, Cleaning Cloth, Dish Sponge, Scouring Wire, Dish Gloves, Trolley Scrubber, Non-Tearing Paper Towel, Trash Bag, Washing Line-Latch, Latex Gloves, Sink Opener, WC Matic, Shoe Sponge, Cotton Stick, Bath Washcloth, Candle, Plastic Cup- Plate - Fork - Spoon - Knife - Mixer - Bowl - Straw, Paper Cup - Plate, Foam Cup - Plate - Set, Aluminum Container, Toothpicks, Wooden Skewer Skewers - Adana Skewers - Mixer - Tongs - Spoon - Spatula - Mortar - Fork - Roller - Cutting Board - Bunch of Kindling, Cleaning Brush - Handle, Plastic Glass Sieve - Squeegee - Hanger - Dustpan - Toilet Paper Holder - Cup - Soap Dispenser - Funnel - Grater - Lemon Squeezer - B Adya, Vegetable and Fruit Peeler, Dough Cutter, Jug, Suction Cup Pump, Cream Pump, Cookie Mold, Plastic Flasks, Charcoal, Fan, Grill Wire, Grill, Igniting Gel Packaging and Sales

is audited by TCS Certification and applied Quality Management System meet the requirements of

ISO 9001:2015

standard complies with the above scope.

Certificate No: QM-00 90 200161-TR

Certificate Date 09.09.2020

Certificate Last Issue Date 09.09.2021

Validity Date of Current Certification Period 09.09.2020 - 09.09.2023

CERTIFICATE VALİDİTY DATE: 09.09.2022

INSPECTION TRUST TRAINING TCS SYSTEM DEPARTMENT

APPROVAL

Barbaros Mah. Halk Cad. Kent Sokak No: 10 Ataşehir / İSTANBUL
T: 0216 573 55 53 F: 0216 573 88 01 info@tcscert.com www.tcscert.com

CERTIFICATE

ÇİFTÇİLER BİRLİK KAĞITÇILIK ANONİM ŞİRKETİ - SAKARYA BRANCH

3. Organize Sanayi Bölgesi, 10. Yol, No:79, Söğütlü, Sakarya, TÜRKİYE

i. Underpad, Adult Diaper, Absorbent Panty/ Pull up Adult Pants, Baby Diaper, Baby Changing Mat, Dog Training Pad Wet Towel, Body Cleaning Towel, Perineum Cleaning Towel, Antibacterial Wet Towel, Wet Toilet Paper, Examination Table Cover, Surface Cleaning Towel -Tissues, Toilet Paper, Towel Paper, Napkin, Dispenser Napkin, Dispenser Towel, Emotion Towel, Centerfeed Towel, Centerfeed Toilet Paper,Pet Cleaning Wipes Production and Sales

ii.Toilet Seat Cover, Wound and Skin Cleaning Towel, Patient Washcloth, Body Washing Bag, Hair Wash Cap, Surgical Face Mask, Cling Film, Aluminum Foil, Refrigerator Bag, Ice Bag, Fireproof Baking Bag, Baking Paper, Under-Cake Capsule, Muffin Mold, Stainless Steel Cutlery - Spoon - Tongs - Tea Plate, Metal Strainer, Metal Nuts - Walnut Crusher, Cleaning Cloth, Dish Sponge, Scouring Wire, Dish Gloves, Trolley Scrubber, Non-Tearing Paper Towel, Trash Bag, Washing Line-Latch, Latex Gloves, Sink Opener, WC Matic, Shoe Sponge, Cotton Stick, Bath Washcloth, Candle, Plastic Cup- Plate - Fork - Spoon - Knife - Mixer - Bowl - Straw, Paper Cup - Plate, Foam Cup - Plate - Set, Aluminum Container, Toothpicks, Wooden Skewer Skewers - Adana Skewers - Mixer - Tongs - Spoon - Spatula - Mortar - Fork - Roller - Cutting Board - Bunch of Kindling, Cleaning Brush - Handle, Plastic Glass Sieve - Squeegee - Hanger - Dustpan - Toilet Paper Holder - Cup - Soap Dispenser - Funnel - Grater - Lemon Squeezer - B Adya, Vegetable and Fruit Peeler, Dough Cutter, Jug, Suction Cup Pump, Cream Pump, Cookie Mold, Plastic Flasks, Charcoal, Fan, Grill Wire, Grill, Igniting Gel Packaging and Sales

is audited by TCS Certification and applied Medical Devices Management System meet the requirements of

ISO 13485:2016

standard complies with the above scope.

Certificate No: MDM-00 90 200161-TR

Certificate Date 09.09.2020

Certificate Last Issue Date 09.09.2021

Validity Date of Current Certification Period 09.09.2020 - 09.09.2023

CERTIFICATE VALIDITY DATE: 09.09.2022

INSPECTION PRODUCT TRAINING SYSTEM TCS SYSTEM DEPARTMENT

APPROVAL

Barbaros Mah. Halk Cad. Kent Sokak No: 10 Ataşehir / İSTANBUL
T: 0216 573 55 53 F: 0216 573 88 01 info@tcscert.com www.tcscert.com

CERTIFICATE

ÇİFTÇİLER BİRLİK KAĞITÇILIK ANONİM ŞİRKETİ - SAKARYA BRANCH

3. Organize Sanayi Bölgesi, 10. Yol, No:79, Söğütlü, Sakarya, TÜRKİYE

i. Underpad, Adult Diaper, Absorbent Panty/ Pull up Adult Pants, Baby Diaper, Baby Changing Mat, Dog Training Pad Wet Towel, Body Cleaning Towel, Perineum Cleaning Towel, Antibacterial Wet Towel, Wet Toilet Paper, Examination Table Cover, Surface Cleaning Towel -Tissues, Toilet Paper, Towel Paper, Napkin, Dispenser Napkin, Dispenser Towel, Emotion Towel, Centerfeed Towel, Centerfeed Toilet Paper,Pet Cleaning Wipes Production and Sales

ii.Toilet Seat Cover, Wound and Skin Cleaning Towel, Patient Washcloth, Body Washing Bag, Hair Wash Cap, Surgical Face Mask, Cling Film, Aluminum Foil, Refrigerator Bag, Ice Bag, Fireproof Baking Bag, Baking Paper, Under-Cake Capsule, Muffin Mold, Stainless Steel Cutlery - Spoon - Tongs - Tea Plate, Metal Strainer, Metal Nuts - Walnut Crusher, Cleaning Cloth, Dish Sponge, Scouring Wire, Dish Gloves, Trolley Scrubber, Non-Tearing Paper Towel, Trash Bag, Washing Line-Latch, Latex Gloves, Sink Opener, WC Matic, Shoe Sponge, Cotton Stick, Bath Washcloth, Candle, Plastic Cup- Plate - Fork - Spoon - Knife - Mixer - Bowl - Straw, Paper Cup - Plate, Foam Cup - Plate - Set, Aluminum Container, Toothpicks, Wooden Skewer Skewers - Adana Skewers - Mixer - Tongs - Spoon - Spatula - Mortar - Fork - Roller - Cutting Board - Bunch of Kindling, Cleaning Brush - Handle, Plastic Glass Sieve - Squeegee - Hanger - Dustpan - Toilet Paper Holder - Cup - Soap Dispenser - Funnel - Grater - Lemon Squeezer - B Adya, Vegetable and Fruit Peeler, Dough Cutter, Jug, Suction Cup Pump, Cream Pump, Cookie Mold, Plastic Flasks, Charcoal, Fan, Grill Wire, Grill, Igniting Gel Packaging and Sales

is audited by TCS Certification and applied Good Manufacturing Practices meet the requirements of

ISO 22716:2007 (GMP)

standard complies with the above scope.

Certificate No: GMP-00 90 200161-TR

Certificate Date 09.09.2020

Certificate Last Issue Date 09.09.2021

Validity Date of Current Certification Period 09.09.2020 - 09.09.2023

CERTIFICATE VALİDİTY DATE: 09.09.2022

INSPECTION PRODUCT TCS SYSTEM DEPARTMENT TRAINING SYSTEM

APPROVAL

Barbaros Mah. Halk Cad. Kent Sokak No: 10 Ataşehir / İSTANBUL
T: 0216 573 55 53 F: 0216 573 88 01 info@tcscert.com www.tcscert.com

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*

Design, Manufacturing, Sterilization and Distribution of Disposable Medical Devices.
Design, Manufacturing and Distribution of Devices for Aspiration, Devices for Vacuum Extraction, Surgical Lights, Examination Lights, Surgical Tables, Orthopedic Traction Systems, Stretchers, Gynecological Tables, Blood Donor Chairs, Eye Surgical Tables, I.V. Stand, Examination Tables.

Reg.-Nr. / *Reg.-No.* 04 221 980886
Bericht Nr. / *Report No.* 3529 9434

Gültigkeit / *Validity*
von / *from* 2021-09-17
bis / *until* 2024-09-16
Edition 7

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-09-16

Die Gültigkeit kann unter https://www.tuev-nord.de/de/unternehmen/zertifizierung/zertifikatsdatenbank verifiziert werden.
Validity can be verified at https://www.tuev-nord.de/de/unternehmen/zertifizierung/zertifikatsdatenbank.

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

CERTIFICATE
of Registration

This is to Certify that the

Medical Devices – Quality Management System

of

MEDCARE SAĞLIK ÜRÜNLERİ SANAYİ VE TİCARET ANONİM ŞİRKETİ

FATİH MAH. ÇAMLIK CAD. NO:54
GAZİEMİR / İZMİR / TÜRKİYE

has been independently assessed and is compliant with the requirements of

ISO 13485:2016

This Certificate is applicable to the following product or service ranges:

PRODUCTION AND SALES OF STERILE AND NON -STERILE MEDICAL TEXTILE PRODUCTS

STERİL VE NON- STERİL MEDİKAL TEKSTİL ÜRÜNLERİ ÜRETİMİ VE SATIŞI

:: Certificate No :: TR52746H

Date of initial registration	**29 June 2020**
Date of this Certificate	**29 June 2020**
Surveillance audit on or before	**28 June 2021**
Recertification Due / Certificate expiry	**28 June 2023**

Director

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