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)
- Sterile Wound) - Class IIa
- Sterile Drain Suction Set (Yankuer Set) Vacuum/
- 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: 2021.09.26 14:43:03 EEST
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

CERTIFICATE

AT Sertifikası

Üretim Kalite Güvence Sistemi

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V

Sertifika Numarası: 1984-MDD-18-508

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:

CEREN ÜRETİM PLASTİK ÜRÜNLERİ SANAYİ VE TİCARET ANONİM ŞİRKETİ

Zafer Mah. 143 Sok. No.8a- 8/3 Esenyurt, İstanbul, Türkiye

Ürünler: Tek Kullanımlık Steril ve Steril Olmayan Anastezi ve Drenaj Ürünleri

Ürünler, sertifikanın bir parçası olan ekte tanımlanmış olup, ek iki 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.4428.06
İlk Yayım Tarihi:	24 Nisan 2018
Son Yayım Tarihi:	03 Eylül 2020
Revizyon Numarası:	02
Son Geçerlilik Tarihi:	27 Mayıs 2024

Kiwa Belgelendirme Hizmetleri A.Ş., bu sertifika kapsamındaki Sınıf Im ürünler cihazlar için Tıbbi Cihaz Yönetmeliği Ek V'e uygun olarak metrolojik şartlara sahip cihazların uygunluğu ile ilgili üretim yönleri ve Sınıf Is cihazlar için 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

03 Eylül 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

AT Sertifikası Eki:

Üretim Kalite Güvence Sistemi

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V

Sertifika No: 1984-MDD-18-508, Revizyon Numarası:02

İlgili tıbbi cihazlar;

Ürün: Nazal Oksijen Kanülü
Model Numarası: A-2030 2006, P-2030 2007, I-2030 2018

Ürün: Oksijen Maskesi
Model Numarası: A-2030 2003, P-2030 2004, I-2030 2005

Ürün: Rezervuarlı Oksijen Maskesi
Model Numarası: A-2030 2011, P-2030 2012

Ürün: Steril ve Steril Olmayan Oksijen bağlantı Hortumu
Model Numarası: S2020 2070, NS2020 2070

Ürün: Nebulizer Set
Model Numarası: A-2030 2008, A-2030 2013, P-2030 2009, P-2030 2014, I-2030 2010

Ürün: Ağızlıklı Nebulizer Set
Model Numarası: 2030 2019, 2030 2020

Ürün: Steril Vajinal Spekulum
Model Numarası: S2060 111, S2060 112, S2060 113

Ürün: Steril Aspirasyon Seti
Model Numarası: S2050 211, S2050 212, S2050 214, S2050 215

Ürün: Steril Kamera Kılıfı
Model Numarası: S2016 020

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

03 Eylül 2020, İstanbul, Türkiye

Kiwa Belgelendirme Hizmetleri A.Ş.
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CERTIFICATE

AT Sertifikası Eki:

Üretim Kalite Güvence Sistemi

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V

Sertifika No: 1984-MDD-18-508, Revizyon Numarası: 02

İlgili tıbbi cihazlar;

Ürün: Steril Aspirasyon Hortumu
Model Numarası: S2050 222, S2050 223, S2050 224, S2050 225

Ürün: Steril Göğüs Drenaj Seti
Model Numarası: S2014 305, S2014 304

Ürün: Steril İdrar Torbası - Pediatrik
Model Numarası: S2010 2012, S2010 2011

Ürün: Steril Smear Fırçası
Model Numarası: S2013 304, S2013 305

Ürün: Atomizer Chamber
Model Numarası: S-2030-2060, M-2030-2061, L-2030-2062

Ürün: Steril Olmayan Kusmuk Torbası
Model Numarası: 2016 010

Ürün: Steril Olmayan Suni Solunum Cihazı
Model Numarası: ALS 2030 2070, AMS 2030 2071, ASS 2030 2072, AL 2030 2070, AM 2030 2071, AS 2030 2072

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

03 Eylül 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-18-508

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:

CEREN ÜRETİM PLASTİK ÜRÜNLERİ SANAYİ VE TİCARET ANONİM ŞİRKETİ

Zafer Mah. 143 Sok. No.8a- 8/3 Esenyurt, Istanbul, Turkey

Products: Disposable Sterile and Non-Sterile Anaesthesia and Drainage Products

The products defined at the enclosure which is the part of this certificate and contains two page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.4428.06
Date of first issue: 24 April 2018
Date of last issue: 03 September 2020
Revision Number: 02
Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements for Class Im devices and with securing and maintaining sterile conditions in accordance with MDD Annex V for Class Is devices covered by this certificate and found that the quality system meets the applicable requirements in MDD Annex V.

Muhteşem Gökhan Yücel
Head of Notified Body

03 September 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

CERTIFICATE

Enclosure of the EC Certificate:

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

Certificate Number: 1984-MDD-18-508, Revision Number: 02

Concerned medical devices;

Product: Nasal Oxygen Cannula
Model Number: A-2030 2006, P-2030 2007, I-2030 2018

Product: Oxygen Mask
Model Number: A-2030 2003, P-2030 2004, I-2030 2005

Product: Oxygen Mask With Reservoir
Model Number: A-2030 2011, P-2030 2012

Product: Sterile and Non-Sterile Oxygen Connection Line
Model Number: S2020 2070, NS2020 2070

Product: Nebulizer Set
Model Number: A-2030 2008, A-2030 2013, P-2030 2009, P-2030 2014, I-2030 2010

Product: Nebulizer Set with Mouthpiece
Model Number: 2030 2019, 2030 2020

Product: Sterile Vaginal Speculum
Model Number: S2060 111, S2060 112, S2060 113

Product: Sterile Suction Kit
Model Number: S2050 211, S2050 212, S2050 214, S2050 215

Product: Sterile Camera Cover
Model Number: S2016 020

Muhteşem Gökhan Yücel
Head of Notified Body

03 September 2020, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
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Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

CERTIFICATE

Enclosure of the EC Certificate:

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

Certificate Number: 1984-MDD-18-508, Revision Number: 02

Concerned medical devices;

Product: Sterile Suction Tube
Model Number: S2050 222, S2050 223, S2050 224, S2050 225

Product: Sterile Thorax Drainage Set
Model Number: S2014 305, S2014 304

Product: Sterile Urine Bag - Pediatric
Model Number: S2010 2012, S2010 2011

Product: Sterile Smear Brush
Model Number: S2013 304, S2013 305

Product: Atomizer Chamber
Model Number: S-2030-2060, M-2030-2061, L-2030-2062

Product: Non-Sterile Vomit Bag
Model Number: 2016 010

Product: Non Sterile Artificial Respirator
Model Number: ALS 2030 2070, AMS 2030 2071, ASS 2030 2072, AL 2030 2070, AM 2030 2071, AS 2030 2072

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

03 September 2020, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
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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*

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 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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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*

Benannt durch/Designated by
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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

Zertifizierungsstelle für Medizinprodukte
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Essen, 2020-04-20

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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 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

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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 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

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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

CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-10-075

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

METKO MEDİKAL VE TIBBİ CİHAZLAR DIŞ TİCARET LİMİTED ŞİRKETİ

İvedik OSB Ağaç İşleri San. Sitesi 1354. Cadde 1358. Sokak No:9 06378 Yenimahalle, Ankara, Turkey

Products: Sterile and Non-Sterile Pulse Oximetry (SpO2) Sensors and Medical Temperature Probes, Sterile Disposable Pressure Transducer

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

Report Number:	M.3393.10
Date of first issue:	23 December 2010
Date of last issue:	16 April 2019
Revision Number:	09
Expiry Date:	20 November 2020

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

16 April 2019, Istanbul, Turkey

Head of Notified Body

Kiwa 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@kiwa.com.tr

SERTİFİKA

Üretim Kalite Güvence

93/42/AT Tıbbı Cihaz Direktifi Ek V

Firma Adı : Honnes Sağlık ve Endüstriyel Ürünleri A.Ş.

Firma Adresi : Cumhuriyet Mah. Karayel Sokak No:14 Çayırova KOCAELİ / TÜRKİYE

İlgili Yönetmelikler ve Ekler : 93/42/AT Tıbbi Cihazlar Yönetmeliği - Ek V

Ürünler : Steril Hazır Pansuman Örtü(Nonwoven poliüretan) - Sınıf Is
Steril Göz Pedi - Sınıf Is
Steril Hemostatik Bası Bandı - Sınıf Is
Steril Kateter Sabitleme Bandı - Sınıf Is
- Nonwoven, şeffaf
- Poliüretan nonwoven pedli
- Şeffaf pedli
- Poliüretan pedli

GMDN : 34864, 11661

Sertifika Numarası	: M.2018.106.9658
Rapor Numarası	: MD.3508.YB
İlk Belgelendirme Denetimi	: 19.01.2016
Tescil Tarihi	: 10.05.2018
Yeniden Belgelendirme Denetimi	: 05.12.2018
Yeniden Belgelendirme Tarihi/No	: 27.02.2019/01
Revizyon Tarihi/No	: -
Geçerlilik Tarihi	: 07.02.2024

APPROVED 2292

UDEM Uluslararası Belgelendirme
Denetim Eğitim Merkezi
San. ve Tic. A.Ş.

UDEM, Listeli ürünlerin 93/42/AT direktifi Ek V, gerekliliklerinin karşıladığını beyan eder. Yukarıda adı geçen üretici Kalite Güvence Sistemi uyguladığını ve Ek v madde 4'e göre periyodik gözetim denetimleri ile sürekliliğini sağlayacağını beyan eder. Belge kapsamında yer alan sınıf I ürünler ile ilgili UDEM'in sorumluluğu ürün steril ise, steril şartların güvence altına alınması ve sürdürülmesi ile ilgili imalat konuları; ölçüm fonksiyonlu ise, ürünlerin metrolojik gereklere uygunluğuyla ilgili imalat konuları ile sınırlıdır. Bu belgenin mülkiyet hakkı UDEM Uluslararası Belgelendirme Denetim Eğitim San. Ve Tic. A.Ş.'ye aittir ve istenildiğinde iade edilmelidir. Yukarıda adı geçen firma ve UDEM bu belgenin bir kopyasını Tescil tarihinden itibaren 5 yıl süre ile muhafaza etmelidir. CE Markalamanın kullanımı üretici beyanı ile firma Sorumluluğundadır. Adı geçen firma onaylanmış ürün ile ilgili bütün değişiklikleri UDEM'e bildirmek zorundadır. UDEM bu belgenin geçerliliğini yenilemezse adı geçen firma söz konusu ürünün piyasaya arzını durduracaktır. Belgenin geçerliliğini www.udem.com.tr internet sayfasından kontrol edebilirsiniz.

CE 2292

Adres: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TÜRKİYE
Tel: +90 312 443 03 90 **Faks:** +90 312 443 03 76
E-posta: info@udemltd.com.tr www.udem.com.tr

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 certificate 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

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

EC Certificate

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

TÜVRheinland®

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 - 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®

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

Date: 2020-05-26

Fuxiu Sheng

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

SERTİFİKA

Tam Kalite Güvence Sistemi

93/42/AT Tıbbi Cihazlar Direktifi Ek II

Firma Adı : Kordon Tıp Sağlık Araç Gereçleri Müh. Prj. İth. San. Tic. Ltd. Şti.

Firma Adresi : 10006/1 Sokak No:43 A.O.S.B. Çiğli İZMİR / TÜRKİYE

İlgili Yönetmelikler ve Ekler : MDD 93/42/AT Tıbbi Cihazlar Yönetmeliği - Ek II (Madde 4 Hariç)

Ürünler : Etilen Oksit Sterilizatörü – Sınıf IIb
Etilen Oksit Sterilizasyon Kartuşları – Sınıf IIb
Etilen Oksit Sterilizasyon Kartuş Kitleri – Sınıf IIb

Ürün Çeşitleri Ek'tedir.

Sertifika Numarası	: M.2017.106.7586
Rapor Numarası	: MD.3232.IB
İlk Belgelendirme Denetimi	: 14.10.2016
Tescil Tarihi	: 17.01.2017
Revizyon Tarihi/No	: -
Geçerlilik Tarihi	: 16.01.2022

UDEM Uluslararası Belgelendirme
Denetim Eğitim Merkezi
San. ve Tic. Ltd. Şti.

UDEM, Listeli ürünlerin 93/42/AT direktifi Ek II, madde 4 hariç gerekliliklerinin karşıladığını beyan eder. Yukarıda adı geçen üretici Kalite Güvence Sistemi uyguladığını ve Ek II madde 5'e göre periyodik gözetim denetimleri ile sürekliliğini sağlayacağını beyan eder.Sınıf III olarak piyasaya arz edilecek ürünler için Ek II madde 4'e göre AT Tasarım İnceleme sertifikası gereklidir. Bu belgenin mülkiyet hakkı UDEM Uluslararası Belgelendirme Denetim Eğitim San. ve Tic.Ltd.Şti.'ye aittir ve istenildiğinde iade edilmelidir. Yukarıda adı geçen firma ve UDEM bu belgenin bir kopyasını Tescil tarihinden itibaren 5 yıl süre ile muhafaza etmelidir.CE Markalamanın kullanımı üretici beyanı ile firma sorumluluğundadır.Adı geçen firma onaylanmış ürün ile ilgili bütün değişiklikleri UDEM'e bildirmek zorundadır. UDEM bu belgenin geçerliliğini yenilemezse adı geçen firma söz konusu ürünün piyasaya arzını durduracaktır. Belgenin geçerliliğini www.udemltd.com.tr internet sayfasından kontrol edebilirsiniz.

CE 2292

Adres: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TÜRKİYE
Tel: +90 312 443 03 90 **Faks:** +90 312 443 03 76
E-posta: info@udemltd.com.tr www.udemltd.com.tr

UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. Ltd. Şti. 2292 Kimlik Numarası ile 93/42/EEC Tıbbi Cihazlar Yönetmeliği'nde Onaylanmış Kuruluş olarak faaliyet göstermekte olup, Bu bir sayfalık doküman "Kordon Tıp Sağlık Araç Gereçleri Müh. Prj. İth. San. Tic. Ltd. Şti." firmasına düzenlenmiş olan 17.01.2017 Tescil Tarihli M.2017.106.7586 Numaralı Belge'nin Eki'dir.

Etilen Oksit Sterilizatörü	Etilen Oksit Sterilizasyon Kartuşları	Etilen Oksit Sterilizasyon Kartuş Kitleri
Model	Model	Model
AX 60	AX 5	AR 5
AX 135	AX 6	AR 6
AX 160	AX 7	AR 7
AX 200	AX 8	AR 8
AX 225	AX 9	AR 9
AX 400	AX 10	AR 10
AX 450	AX 11	AR 11
AX 1000	AX 12	AR 12
AX 2000	AX 13	AR 13
AX 4000	AX 14	AR 14
AX 6000	AX 15	AR 15
AX 9000	AX 16	AR 16
	AX 17	AR 17
	AX 18	AR 18
	AX 19	AR 19
	AX 20	AR 20
	AX 21	AR 21
	AX 22	AR 22
	AX 23	AR 23
	AX 24	AR 24
	AX 25	AR 25
	AX 26	AR 26
	AX 27	AR 27
	AX 28	AR 28
	AX 29	AR 29
	AX 30	AR 30
	AQ 5	ARQ 5
	AQ 6	ARQ 6
	AQ 7	ARQ 7
	AQ 8	ARQ 8
	AQ 9	ARQ 9
	AQ 10	ARQ 10
	AQ 11	ARQ 11
	AQ 12	ARQ 12
	AQ 13	ARQ 13
	AQ 14	ARQ 14
	AQ 15	ARQ 15
	AQ 16	ARQ 16
	AQ 17	ARQ 17
	AQ 18	ARQ 18
	AQ 19	ARQ 19
	AQ 20	ARQ 20
	AQ 21	ARQ 21
	AQ 22	ARQ 22
	AQ 23	ARQ 23
	AQ 24	ARQ 24
	AQ 25	ARQ 25
	AQ 26	ARQ 26
	AQ 27	ARQ 27
	AQ 28	ARQ 28
	AQ 29	ARQ 29
	AQ 30	ARQ 30
	AL 7	
	AL 25	
	AL 67	
	AL 100	
	AX 67	
	AX 100	
	AX 127	
	AX 134	
	AQ 70	
	AQ 120	
	AQ 130	
	AQ 170	
	AQ 200	
	AQ 230	

UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. Ltd. Şti.

CERTIFICATE

ÇİFTÇİLER BİRLİK KAĞITÇILIK ANONİM ŞİRKETİ

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

Tek Kullanımlık Kullan-At Ürünleri (Streç Film, Alüminyum Folyo, Buzdolabı Poşeti, Pişirme Kağıdı, Hidrofil Pamuk, Pamuklu Çubuk, Plastik Tabak, Kaşık, Çatal, Bardak, Çöp Şiş, Mum, Naftalin, Çöp Poşeti, Alüminyum Kaplar, Lavabo Açıcı, Temizlik Bezi, Pipet, Yatak Koruyucu Örtü,Kaydırmaz Bantlı Yatak Koruyucu Örtü, Hasta Bezi, Emici Külot Hasta bezi, Bebek Bezi, Alt Değiştirme Örtüsü, Hayvan Alıştırma Pedi, Islak Havlu, Tuvalet Kağıdı, Jumbo Tuvalet Kağıdı, Havlu Kağıt,Islak Mendil, Mendil,Peçete, Muayene Masa Örtüsü, Dispenser Peçete, Dispenser Havlu, Hareketli Havlu, İçten Çekmeli Tuvalet Kağıdı, İçten Çekmeli Havlu, Klozet Kapak Örtüsü, Yara ve Cilt Temizleme Havlusu, Saç Yıkama Bonesi, Polyester ve Viskon Kumaştan Temizlik Bezi, Tekstil Yüzeyli Hasta Bezi, Hasta Lifi, Vücut Temizleme Havlusu, Vücut Yıkama Kesesi, Perine Temizleme Havlusu) Üretimi ve Satışı

Production and Sales of Disposable Products (Stretch Film, Aluminum Foil, Freezer Bag, Baking Paper, Hydrophilic Cotton, Cotton Stick, Plastic Plate-Spoon-Fork-Glass ,Cup, Garbage Skewers, Candle, Naphthalene, Garbage Bag, Aluminum Containers, Sink Opener, Cleaning Cloth, Pipette, Underpad, Non-Slip Underpad, Adult Diaper, Pull Up Adult Diaper, Baby Diaper, Baby Diaper Changing Mat, Dog Training Pad, Wet Towel,Toilet Paper, Jumbo Toilet Paper, Kitchen Towel, Wet Wipes, Handkerchief, Napkin, Examination Table Cloth, Dispenser Napkin, Dispenser Towel, Emotion Towel, Centerfeed Toilet Paper, Centerfeed Towel, Toilet Seat Cover Cloth, Wound and Skin Cleaning Towel, Hair Wash Cap, Polyester and Viscose Cleaning Cloth, Textile Surface Adult Diaper, Hygenic Fiber, Body Cleaning Towel, Perineal Area Cleaning Towel

TCS Belgelendirme tarafından denetlenmiş ve uygulamakta olduğu Medikal Cihaz Yönetim Sisteminin
is audited by TCS Certification and applied Medical Devices Management System meet the requirements of

ISO 13485:2016

standardına aşağıdaki kapsamda uymakta olduğu gözlenmiştir.
standard for the following activities.

Sertifika No / *Certificate No:* **MDM-00 90 180661-TR**

Sertifika İlk Yayın Tarihi / *Certificate Date* 28.09.2018

Sertifika Son Basım Tarihi / *Certificate Last Issue Date* 17.10.2019

Mevcut Belgelendirmenin Geçerlilik Periyodu / *Validity Date of Current Certification Period* 28.09.2018-28.09-2021

INSPECTION PRODUCT TRAINING TCS SYSTEM DEPARTMENT

SERTİFİKA GEÇERLİLİK TARİHİ : 28.09.2021

ONAY
APPROVAL

Kocasinan Cad. Yanardağ Sk. No: 9/11 Küçükbakkalköy Ataşehir / İstanbul
T: 0216 573 55 53 F: 0216 573 88 01 info@tcscert.com www.tcscert.com

Ref. Certif. No.

FI-18868

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE

CERTIFICAT D'ESSAI OC

Product Produit	**Alternating Pressure Mattress**
Name and address of the applicant Nom et adresse du demandeur	Guangdong Yuehua Medical Instrument Factory Co., Ltd. Rongsheng Science and Technology Zone, Daxue Road, Shantou, Guangdong, China
Name and address of the manufacturer Nom et adresse du fabricant	Same as applicant
Name and address of the factory Nom et adresse de l'usine	Same as applicant
Note *When more than one factory, please report on page 2* Note *Lorsque il y plus d'une usine, veuillez utiliser la 2ème page*	☐ Additional Information on page 2
Ratings and principal characteristics Valeurs nominales et caractéristiques principales	230 V a.c.; 50 Hz / 60 Hz; 0,1 A; IP21; Class II
Trademark (if any) Marque de fabrique (si elle existe)	YHMED
Type of Manufacturer's Testing Laboratories used Type de programme du laboratoire d'essais constructeur	—
Model / Type Ref. Ref. De type	QDC-303, QDC-300, QDC-301, QDC-500, QDC-501, QDC-800, QDC-303B, QDC-300B, QDC-301B, QDC-500B, QDC-501B, QDC-800B
Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire., peuvent être indiqués sur la 2ème page	— ☐ Additional Information on page 2
A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la	IEC 60601-1: 2005 + A1: 2012 (Ed.3.1) IEC 60601-1-11: 2010 (Ed.1.0) IEC 60601-1-6: 2010 + A1: 2013 (Ed. 3.1) IEC 62366: 2007 + A1: 2014(Ed. 1.1) National Differences: —
As shown in the Test Report Ref. No. which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat	GZME150500038201 GZME150500038202 GZME150700068701 GZME150700068702

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de Certification

SGS Fimko Ltd.
Särkiniementie 3
FI-00210 Helsinki, Finland

Signature:

Jason Hoo

SGS Fimko Ltd.

Date: 2015-09-10

ÇİFTÇİLERBİRLİK
KAĞITÇILIK HİJYENİK ÜRÜNLER ve YAĞ SAN. A.Ş.

Orta Mahallesi ,Marifet Sokak, No: 15/1A Kartal / İstanbul-Turkey
Tel: +90 (216) 451 00 00 Fax: +90 (216) 452 00 00
info@cihangroup.com - www.cihangroup.com

CE

EC DECLARATION OF CONFORMITY

Medical Devices Directive 93/42/EEC

We,

ÇİFTÇİLER BİRLİK KAĞITÇILIK ANONİM ŞİRKETİ
Herewith declare that Adult Diaper, Underpad and Pull Up Adult Pants for medical use

FLEXI LIFE (MEDIUM, LARGE, X LARGE)
FLEXI LIFE PLUS (MEDIUM, LARGE, X LARGE)

are produced in our manufacturing place,

ÇİFTÇİLER BİRLİK KAĞITÇILIK ANONİM ŞİRKETİ
3.Organize Sanayi Bölgesi, 10.Yol , No: 79
Söğütlü Sakarya Turkey

according to harmonize standards,

TS EN ISO 13485:2016 –TS EN ISO 9001:2015 – TS EN ISO 22716:2007 (GMP)

and according to

Medical Devices Directive 93/42/EEC Annex VII Declaration of Conformity Product Classification: Class 1 (93/42/EEC Annex IX, Rule 1)

Issued Date : 28.10.2019
ISTANBUL

CERTIFICATE

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the company

IT Dr. Gambert GmbH

Scope of certification:

Design and development, manufacture and distribution of electro-chemical gas sensors for medical equipment

Certified location:

Hinter dem Chor 21, 23966 Wismar, Germany

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50403-Z6-00.

This certificate is valid from 2018-09-17 to 2021-09-16

Registration No.: 50403-14-00

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15, D-70565 Stuttgart

DEKRA Certification

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-08-31

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

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

MANAGEMENT SYSTEM
ISO/IEC 17021-1:2015
NAC-002-MS

Certificate of Registration

This is to certify that

Quality Management System
for Medical Devices

of

KORDON TIP SAĞLIK ARAÇ GEREÇLERİ
MÜHENDİSLİK PROJE İTHALAT LTD. ŞTİ.

10006/1 NO:43 A.O.S.B. ÇİĞLİ - İZMİR / TÜRKİYE
Branch: 354. SOK NO:4 2. SANAYİ SİTESİ BORNOVA - İZMİR / TURKEY

complies with requirements of

ISO 13485:2016

This certificate is valid concerning all activities related to;

MANUFACTURING, DESIGN AND SALES OF ETHYLENE OXIDE STERILIZERS AND ETHYLENE OXIDE CARTIDGES. PRODUCT REALIZATION AND SALES OF BIOLOGICAL INDICATORS, STERILIZATION REELS, CHEMICAL INDICATORS, AUTOCLAVE TAPES, STERILIZATION DOCUMENTATION LABEL CHEMICAL INDICATORS, ETHYLENE OXIDE CARTRIDGE STORAGE CONTAINERS, WASHER INDICATORS, AUTOMATIC CARTRIDGE ACTIVATORS AND CONTAINERS, ETHYLENE OXIDE DETECTORS, AUTOCLAVEABLE BIOHAZARD BAGS, PATIENT TRANSFER SYSTEM, BOWIE & DICK TEST PACKS, WRAP PAPERS, BIOLOGICAL INDICATOR INCUBATORS, CHEMICAL VAPOR INDICATOR CLASS V FEED,EO INDICATOR CHEMICAL CLASS V FEED, RESIDUAL PROTEIN TEST, ULTRASONIC WASHING INDICATOR, STERILIZATION ENVELOPES,SELF ADHESIVE CHEMICAL THEY INDICATOR, HELIX CARGO CONTROL INDICATOR,LABEL GUN, WASH INDICATOR APPARATUS, PCD APPARATUS, STERILIZATION VALIDATION AND CALIBRATION SERVICE, STERILIZATION REEL SEALING, CUTTING AND PRINTING MACHINE, NEUTRALIZATORS, HEADER BAGS, WORK STATIONS, HANGER – CUTTER APPARATUS

ISO 02 795 488	Jan. 6, 2021	Jan. 2, 2022
Certificate No.	*Date of this Certificate*	*Certification Expiry Date*
Dec. 29, 2020	Jan. 3, 2020	
Date of Audit	*Date of Registration*	*Managing Director / Director*

MDC MEDICERT CERTIFICATE

Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
Tersane Mah. Cemal Gürsel Cad. No:11/3 Halide Hnm. Apt. Karşıyaka / İzmir
Tel: 0232 327 33 44 www.medicert.com.tr info@medicert.com.tr

MANAGEMENT SYSTEM
ISO/IEC 17021-1:2015
NAC-002-MS

Certificate of Registration

Bu Sertifika,

Medikal Cihazlar için
Kalite Yönetim Sistemi

gereksinimlerine uygun olarak

KORDON TIP SAĞLIK ARAÇ GEREÇLERİ MÜHENDİSLİK PROJE İTHALAT LTD. ŞTİ.

10006/1 NO:43 A.O.S.B. ÇİĞLİ - İZMİR / TÜRKİYE
Şube: 354. SOK NO:4 2. SANAYİ SİTESİ BORNOVA - İZMİR / TURKEY

yukarıda adı geçen kuruluşa,

ISO 13485:2016

Şartlarına uygun bir Kalite Yönetim sistemine aşağıda belirtilen kapsam dahilinde sahip olduğunu onaylar;

ETİLEN OKSİT STERİLİZATÖRLERİ VE ETİLEN OKSİT KARTUŞLARI, ÜRETİMİ , TASARIMI VE SATIŞI. BİYOLOJİK İNDİKATÖRLER, STERİLİZASYON RULOLARI, KİMYASAL İNDİKATÖRLER, OTOKLAV BANTLARI, STERİLİZASYON DÖKÜMANTASYON ETİKET KİMYASAL İNDİKATÖRLERİ, ETİLEN OKSİT KARTUŞ SAKLAMA KONTEYNIRI, YIKAMA İNDİKATÖRLERİ, OTOMATİK KARTUŞ AKTİVATÖRLERİ VE KONTEYNIRLARI, ETİLEN OKSİT DEDEKTÖRÜ, OTOKLAVLANABİLİR TIBBİ ATIK TORBASI, HASTA TRANSFER SİSTEMİ, BOWIE & DICK TEST PAKETLERİ, WRAP KAĞITLARI, BİYOLOJİK İNDİKATÖR İNKÜBATÖRÜ, BUHAR KIMYASAL İNDIKATÖR CLASS V İLERLEMELI, EO KİMYASAL İNDIKATÖR CLASS V İLERLEMELI, PROTEİN KALINTI TESTİ, ULTRASONIC YIKAMA İNDİKATÖRÜ, STERİLIZASYON ZARFLARI, KENDİNDEN YAPIŞKANLI KİMYASAL İNDIKATÖRLER, HELIX YÜK KONTROL İNDIKATÖRÜ, ETİKET TABANCASI, YIKAMA İNDIKATÖRÜ APARATLARI , PCD APARATLARI, STERİLIZASYON VALİDASYON VE KALİBRASYON HİZMETİ, STERİLİZASYON RULOSU KAPATMA / KESME VE YAZICI CİHAZLAR, NÖTRALİZATÖRLER, HEADER BAG, ÇALIŞMA İSTASYONLARI, ASKI – KESME APARATI, FASON ÜRETİMİNİN GERÇEKLEŞTİRİLMESİ VE SATIŞI

ISO 02 795 488	Oca. 6, 2021	Oca. 2, 2022
Sertifika No.	*Sertifika Tarihi*	*Sertifika Geçerlilik Tarihi*
Ara. 29, 2020	Oca. 3, 2020	
Denetim Tarihi	*Kayıt Tarihi*	*Genel Müdür*

Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
Tersane Mah. Cemal Gürsel Cad. No:11/3 Halide Hnm. Apt. Karşıyaka / İzmir
Tel: 0232 327 33 44 www.medicert.com.tr info@medicert.com.tr

CERTIFICATE

kiwa

ceren üretim

CEREN ÜRETİM PLASTİK ÜRÜNLERİ SANAYİ VE TİCARET ANONİM ŞİRKETİ

ZAFER MAH. 143. SOK. NO: 8A - 8/3 ESENYURT – İSTANBUL – TÜRKİYE

TEK KULLANIMLIK STERİL VE STERİL OLMAYAN ANESTEZİ, DRENAJ, JİNEKOLOJİ ÜRÜNLERİNİN TASARIMI VE ÜRETİMİ

kapsamında

EN ISO 13485:2016

Tıbbi Cihazlar - Kalite yönetim sistemleri – Düzenleyici amaçlar için gereklilikler

"Standardın aşağıda verilen maddeleri hariç tutulmuştur"
"7.5.3" "7.5.4" "7.5.9.2" "7.5.10"

Sertifika No	: M 11284
İlk Belgelendirme Tarihi	: 05 Temmuz 2019
Yenileme Tarihi	: 05 Temmuz 2019
Son Geçerlilik Tarihi	: 04 Temmuz 2022

Genel Müdür

Kiwa 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: info@kiwa.com.tr

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

Sertifika Son Güncelleme Tarihi : 05 Temmuz 2019 - R 00

TÜRKAK
Medikal Cihazlar K.Y.S.
TS EN ISO/IEC 17021-1
AB-0006-YS

TÜRKAK BDS NO
YS-1D43-339E

CERTIFICATE

ceren üretim

CEREN ÜRETİM PLASTİK ÜRÜNLERİ SANAYİ VE TİCARET ANONİM ŞİRKETİ

ZAFER MAH. 143. SOK. NO: 8A - 8/3 ESENYURT – İSTANBUL – TURKEY

with a scope of

DESIGN AND MANUFACTURING OF DISPOSABLE STERILE AND NON-STERILE ANAESTHESIA, GYNAECOLOGY, DRAINAGE PRODUCTS

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded"
"7.5.3" "7.5.4" "7.5.9.2" "7.5.10"

EN ISO 13485:2016

Certificate No	: M 11284
Initial Certification Date	: 05 July 2019
Renewal Date	: 05 July 2019
Expiration Date	: 04 July 2022

General Manager

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

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

Last Modified: 05 July 2019 - R 00

TÜRKAK
Medical Device Q.M.S.
TS EN ISO/IEC 17021-1
AB-0006-YS

TÜRKAK BDS NO
YS-1D43-339E

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 Zertifizierungsstelle TÜVRheinland

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

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

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

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, YOĞUN BAKIM ÜRÜNLERİNİN ÜRETİMİ, PAKETLENMESİ, STERİLİZASYONU, DEPOLANMASI, DAĞITIMI VE EN ISO 11135 STANDARDINA UYGUN ETİLEN OKSİT STERİLİZASYON HİZMETLERİ

kapsamında

EN ISO 13485:2016

Tıbbi Cihazlar - Kalite yönetim sistemleri – Düzenleyici amaçlar için gereklilikler

"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

Genel Müdür

Kiwa 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: info@kiwa.com.tr

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

TÜRKAK
Medikal Cihazlar K.Y.S.
TS EN ISO/IEC 17021-1
AB-0006-YS

TÜRKAK BDS NO
YS-694E-E7CB

Sertifika Son Güncelleme Tarihi : 03 Ekim 2019 - R 00

SERTİFİKA

Tam Kalite Güvence Sistemi

93/42/AT Tıbbi Cihazlar Direktifi Ek II (Madde 4 Hariç)

Firma Adı : Medbar Tıbbi Malzemeler Turizm San ve Tic. A.Ş.

Firma Adresi : 1142 Sokak No:35 Sarnıç Gaziemir İZMİR / TÜRKİYE

İlgili Yönetmelikler ve Ekler : 93/42/AT Tıbbi Cihazlar Yönetmeliği - Ek II (Madde 4 Hariç)

Ürünler : Fototerapi Göz Bandı - Sınıf Is
Trakeosotomi Kanül Sabitleyici - Sınıf Is
Endotrakeal Tip Sabitleyici - Sınıf Is
El Sabitleyici - Sınıf Is
Ayak Sabitleyici - Sınıf Is
El ve Ayak Sabitleyici Çocuk/Bebek - Sınıf Is
Jinekolojik Toplayıcı - Sınıf Is
Mide Yıkama Seti - Sınıf Im
Arter Kanül - Sınıf IIa

GMDN : 45189, 35752, 35815, 12102, 12094, 12097, 32655, 58985, 34893

Sertifika Numarası	: M.2016.106.7000
Rapor Numarası	: MD.3184.IB
İlk Belgelendirme Denetimi	: 01.07.2016
Tescil Tarihi	: 03.10.2016
Revizyon Tarihi/No	: 10.07.2020/02
Geçerlilik Tarihi	: 02.10.2021

UDEM APPROVED 2292

UDEM Uluslararası Belgelendirme
Denetim Eğitim Merkezi
San. ve Tic. A.Ş.

UDEM, Listeli ürünlerin 93/42/AT direktifi Ek II, madde 4 hariç gerekliliklerinin karşıladığını beyan eder. Yukarıda adı geçen üretici Kalite Güvence Sistemi uyguladığını ve Ek II madde 5'e göre periyodik gözetim denetimleri ile sürekliliğini sağlayacağını beyan eder. Sınıf III olarak piyasaya arz edilecek ürünler için Ek II madde 4'e göre AT Tasarım İnceleme sertifikası gereklidir. Belge kapsamında yer alan sınıf I ürünler ile ilgili UDEM'in sorumluluğu ürün steril ise, steril şartların güvence altına alınması ve sürdürülmesi ile ilgili imalat konuları; ölçüm fonksiyonlu ise, ürünlerin metrolojik gereklere uygunluğuyla ilgili imalat konuları ile sınırlıdır. Bu belgenin mülkiyet hakkı UDEM Uluslararası Belgelendirme Denetim Eğitim San. Ve Tic. A.Ş.'ye aittir ve istenildiğinde iade edilmelidir. Yukarıda adı geçen firma ve UDEM bu belgenin bir kopyasını Tescil tarihinden itibaren 5 yıl süre ile muhafaza etmelidir. CE Markalamanın kullanımı üretici beyanı ile firma sorumluluğundadır. Adı geçen firma onaylanmış ürün ile ilgili bütün değişiklikleri UDEM'e bildirmek zorundadır. UDEM bu belgenin geçerliliğini yenilemezse adı geçen firma söz konusu ürünün piyasaya arzını durduracaktır. Belgenin geçerliliğini www.udem.com.tr internet sayfasından kontrol edebilirsiniz.

Adres: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TÜRKİYE
Tel: +90 312 443 03 90 **Faks:** +90 312 443 03 76
E-posta: info@udemltd.com.tr www.udem.com.tr

Declaration of Conformity

for M03

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	M03
Legal Manufacturer: (Name on Label)	Medical Filtration Solutions Ltd, 72 Roman Way Industrial Estate, Longridge Road, Preston, LANCS, PR2 5BE, UK.
Manufacturer's SRN:	Not Yet Available
Basic UDI-DI:	506055490M03CG
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose	A filter to protect suction / aspirator medical device/ circuit from fluids and secretions from a patient.
MD Regulation Classification:	Class I
Notified Body:	Not Applicable for Class I
EC Certificate:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta. Tel: + 356 2546 6689. Email: info@advenamedical.com
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

Name Karl Howard **Position** Director

Signed  **On the date** 2021-07-20

In Preston, Lancashire, United Kingdom for and on behalf of Medical Filtration Solutions Ltd.

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
Regulation (EU) 2017/745	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
ISO 10079-1:2015	Medical suction equipment. Part 1: Electrically powered suction
EN ISO 20417:2021	Medical Devices- Information to be supplied by the manufacturer.

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
M03.1.003	65mm suction housing, 8mm barb connections	37798
M03.1.004	65mm suction housing, 11-15mm barb connections	37798
M03.1.009	90mm suction housing, 11-15mm barb connections	37798
M03.1.018	65mm suction housing, 11-15mm barb one side and 15mm other side.	37798

Version History

Version	Compiled by	Date	Description
1.0	John Keegan	2019-06-13	First issue
2.0	Karl Howard	2020-12-21	Second Issue- Authorised Representative added for post "Brexit".
3.0	Karl Howard	2021-07-13	Third issue- Changes for transition to Regulation (EU) 2017/745
4.0	Karl Howard	2021-07-20	Updated to address errors and assessment route