By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

3M Poland Sp. z o.o.
Al. Katowicka 117
Nadarzyn
05-830
Poland

Holds Certificate Number: MD 611743

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

Sales and marketing of sterile and non-sterile, active and non-active medical devices

For and on behalf of BSI:

Gary Fenton, Global Assurance Director

Originally registered: 12/06/2014 Latest Issue: 12/06/2014 Expiry Date: 11/06/2017

Digitally signed by Cojocaru Vera
Date: 2021.03.23 02:31:09 EET
Reason: MoldSign Signature
Location: Moldova

...making excellence a habit.™

UKAS MANAGEMENT SYSTEMS 003

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 078535 0038 Rev. 00

Certificate Holder: **3M Deutschland GmbH**
Carl-Schurz-Straße 1
41453 Neuss
GERMANY

Certification Mark:

Scope of Certificate: **Design, Development, Manufacturing and Distribution of Medical and Technical Products for Dentistry, as Impression Materials, Crown and Bridge Materials, Filling Materials, Materials for Prophylaxis, Luting Cements, Endodontic Points and Rotary Instruments, Light Curing Devices, Mixing Devices, Micro-Blasters, Adhesives, Retraction Materials, Dental Materials for Surface Preparation, Varnishes, Dental Cartridge Syringes, Etchants, Impression Trays, Gingiva Modeling Materials, Pattern and Block-Out Resins and Accessories for Dental Medical Devices**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **31-573-1711**

Effective Date: **2019-02-26**

Expiry Date: **2022-02-25**

Date of Issue: 2019-03-18

(Arie Henkin)
Manager, Certification Body MHS
TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

US-Letter / 07.17

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 078535 0038 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820
- 21 CFR Part 821

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):

3M Deutschland GmbH
Carl-Schurz-Straße 1, 41453 Neuss, GERMANY

3M Deutschland GmbH
ESPE Platz, 82229 Seefeld, GERMANY

3M Deutschland GmbH
Ohmstraße 3, 86899 Landsberg, GERMANY

Date of Issue: 2019-03-18

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

TÜV®

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 078535 0038 Rev. 00

Facility Scopes:

3M Deutschland GmbH
Carl-Schurz-Straße 1, 41453 Neuss, GERMANY

Headquarter and Legal Entity
DUNS No: 31-573-1711

3M Deutschland GmbH
ESPE Platz, 82229 Seefeld, GERMANY

Design, Development, Manufacturing and Distribution of Medical and Technical Products for Dentistry, as Impression Materials, Crown and Bridge Materials, Filling Materials, Materials for Prophylaxis, Luting Cements, Endodontic Points and Rotary Instruments, Light Curing Devices, Mixing Devices, Micro-Blasters, Adhesives, Retraction Materials, Dental Materials for Surface Preparation, Varnishes, Dental Cartridge Syringes, Etchants, Impression Trays, Gingiva Modeling Materials, Pattern and Block-Out Resins and Accessories for Dental Medical Devices
DUNS No: 34-269-3340

3M Deutschland GmbH
Ohmstraße 3, 86899 Landsberg, GERMANY

Manufacturing Operations for Dental Cements, Filling Materials, Adhesives and Retraction Pastes, related Accessories and Plastic Parts such as Intraoral Syringes, Mixing Tips, Impression Trays; Incoming Goods Inspection and Processing of Micro-Blasters, Endodontic Points, Rotary Instruments
DUNS No: 34-252-3575

Date of Issue: 2019-03-18

(Arie Henkin)
Manager, Certification Body MHS
TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

TÜV®

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

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 TIBBİ MALZEMELER TURİZM SANAYİ VE TİCARET ANONİM ŞİRKETİ

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

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.5746.01
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

13 Temmuz 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-20-682

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	-

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

13 Temmuz 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

DECLERATION OF CONFORMITY

EC Decleration of Conformity:	MEDiCAL DEViCES DiRECTiVES (93/42/EEC) APPENDiX-Vii
Manufacturer:	HEGELİ ORTOPEDİK ÜRÜNLER SAN. TİC. LTD. ŞTİ
Manufacturer's address:	Cihangir Mah. Şehit Piyade Er Yavuz Bahar Sok. No:4 Mirabbo Sanayi Sitesi D: Blok Kat:3 Ambarlı – Avcılar – İstanbul – Turkey
Device/s:	ORTHOPEDİC SUPPORT PRODUCTS
Description:	MEDiCAL DEViCE(S) THAT SUPPORT(S) THE HUMAN BODY EXTERNALLY.
EC Product Class:	CLASS I

MEDiCAL DEViCES DiRECTiVES (93/42/EEC) - APPENDiX Vii

STANDARDS:

EN 980: 2008:	Graphical symbols for use in the labelling of medical devices.
EN ISO 14971: 2012	Medical devices. Application of risk management to medical devices
EN 1041: 2008 + A1: 2013	information supplied by the manufacturer of medical devices.
EN 14971: 2004:	The risk analysis for medical devices.

HEGELİ ORTOPEDİK ÜRÜNLER SAN. VE TİC. LTD. ŞTİ.

Decleration OF CONFORMiTY

HEGELi ORTHOPEDiCS declares that the medical device(s) listed on the attached Appendix A conform(s) to the relevant provisions of **the MDD 93/42/EEC MEDiCAL WRiTTEN DECREE COUNCiL** conditions.

HEGELi ORTHOPEDiCS confirms that no other application has been lodged with another notified body fort he same device related **QUALiTY MANAGEMENT SYSTEM iSO 9001:2008 and iSO 13485:2003**.

HEGELi ORTHOPEDiCS agrees to develop, implement and maintain a formally-recognised Quality Management System to ensure continued adequacy and efficacy.

HEGELi ORTHOPEDiCS agrees to inform the appointed Notified Body of any planned and unplanned substantial change to the Quality Management System.

HEGELi ORTHOPEDiCS agrees to inform the appointed Notified Body of any planned or unplanned significant change to the Appendix A, including significant design change to the devices.

Signed by the designated representative;

Name: Mr KEMAL ŞAHiN

Title: GENERAL MANAGER

HEGELİ ORTOPEDİ ÜRÜNLER
SAN. ve TİC. LTD. ŞTİ.

Date: 01/01/2014

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

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

ISO 22716:2007 (GMP)

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

Sertifika No / *Certificate No:* **GMP-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 Issued* 28.09.2018-28.09.2021

INSPECTION PRODUCT PLANNING TCS SYSTEM DEPARTMENT

SERTİFİKA GEÇERLİLİK TARİHİ : 28.09.2020

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

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

ISO 9001:2015

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

Sertifika No / *Certificate No:* **QM-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

SERTİFİKA GEÇERLİLİK TARİHİ : 28.09.2020

INSPECTION PRODUCT TRAINING TCS SYSTEM DEPARTMENT

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

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

MINISTERUL SĂNĂTĂŢII, MUNCII ŞI PROTECŢIEI SOCIALE AL REPUBLICII MOLDOVA
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ, ТРУДА И СОЦИАЛЬНОЙ ЗАЩИТЫ РЕСПУБЛИКИ МОЛДОВА
AGENŢIA NAŢIONALĂ PENTRU SĂNĂTATE PUBLICĂ
НАЦИОНАЛЬНОЕ АГЕНТСТВО ОБЩЕСТВЕННОГО ЗДОРОВЬЯ
MD-2028, mun. Chişinău, str. Gheorghe. Asachi, 67-a
Tel. + 373 22 574501, fax + 373 22 729725
IDNO 1018601000021
E-mail: ansp@ansp.md; anticamera@ansp.md

DOCUMENTAŢIE MEDICALĂ / Медицинская документация
FORMULAR / Форма **Nr. 303-2/e**
APROBAT DE MSMPS al RM / Утверждена МЗТСЗ РМ
31.10.11 Nr. 828

Centrul de încercări de laborator acreditat de către Centrul Naţional de Acreditare din Republica Moldova MOLDAC
Испытательный лабораторный центр аккредитованный Национальным Аккредитационным Центром РМ MOLDAC
Certificat nr. LÎ-044 din 17.02.2018 valabil până la 16.02.2022
Acreditat în Sistemul Ministerului Sănătăţii, Muncii şi Protecţiei Sociale al RM
Аккредитованный в системе Министерства Здравоохранения, Труда и Социальной Защиты Республики Молдова
Certificat nr. 2293 din 24.10.2014, valabil până la 24.10.2019

AVIZ SANITAR

PENTRU PRODUSELE ALIMENTARE ŞI NEALIMENTARE Nr. P-6242/2020

Санитарное заключение для пищевых и непищевых продуктов

din/*от* " 17 " iulie a./*г.* 2020

Prin prezentul aviz sanitar se confirmă că producerea, importul, utilizarea şi desfacerea produselor / echipamentelor
Настоящим санитарным заключением подтверждается, что производство, ввоз, использование и реализация продукции / оборудования

Scutece, protector de pat

sunt conforme Regulamentului (lor) sanitar (e) / *соответствуют санитарному (ым) регламенту (ам)* (se va indica denumirea completă a Regulamentului (lor) sanitar (e) / *указать полное наименование санитарного (ых) регламента (ов)*

HG nr.1207 din 02.11.2016, San PiN 42-125-4390-87

Organizaţia-producătoare/importatoare, ţara de origine / *организация произв./импортер, страна происхождения*

Turcia, CIFTCILER BIRLIK KAGITCILIK ANONIM SIRKETI

Destinatarul avizului sanitar / *получатель санитарного заключения*

ÎCS"HEALTH FOREVER INTERNATIONAL" SRL, Moldova, Chişinău, str. M.Varlaam, 77

Ca temei pentru recunoaşterea conformităţii produselor Regulamentului (lor) sanitar (e) menţionat (e) a servit /
Основанием для признания продукции указанному (ым) санитарному (ым) регламенту (ам) послужило

Demers, contract nr.003/2020 din 01.01.2020, facturi, certificat de calitate, ISO, rapoarte a încercărilor de laborator nr.3703-3705 din 06.07.2020

(a enumera documentele de însoţire, buletinele de analiză / *перечислить сопроводительные док., протоколы исслед.)*

Caracteristica sanitară a produselor / *санитарная характеристика продукции:*

Parametrii (factorii) / *показатели (факторы)* **Normativul sanitar** / *санитарный норматив*

conform rapoartelor încercărilor de laborator nr.3703-3705 din 06.07.2020

Domeniu de utilizare / *Область применения:* întreţinere

Condiţiile necesare de utilizare, depozitare, transportare, măsurile de securitate / *Необходимые условия использования, хранения, транспортировки, меры безопасности:*

importul, plasarea pe piaţă în condiţiile respectării legislaţiei în vigoare în Republica Moldova

AVIZUL SANITAR este valabil pînă la / *Санитарное Заключение действительно до:* 30 iulie 2021

DIRECTORUL AGENŢIEI NAŢIONALE PENTRU SĂNĂTATE PUBLICĂ
Nicolae FURTUNĂ

(numele, prenumele/ Ф.И.О.) (semnătura / подпись)

L.Ş.

ANSP/HAO3

SP 10-XVI-09 0002367 O3

ex:Şt.Constantinovici
tel: 574 679

EC Certificate

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

Registration No.: HD 60139711 0001

Report No.: 17047213 009

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

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60101918 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-08-05

Date: 2019-08-05

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

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

Products:

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

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2019-08-05

Fuxiu Sheng

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

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

Aspects of manufacture concerned with securing and maintaining sterile conditions:

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

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-08-05

EG-Zertifikat / *EC-Certificate*

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

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

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

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

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

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

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

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

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

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-07-04

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

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

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

ANLAGE / *ANNEX*

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

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

Produkte der Klasse III
Products of class III

Vent Catheter
Atrial Cannula
Vessel Cannula with / without check valve

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

Bericht Nr. / *Report No.* 3521 8285

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

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

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
Lekocyte Filter Set
Gamma Leukocyte Filter Set

Produkte der Klasse IIa
Products of class IIa

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

Bericht Nr. / *Report No.* 3521 8285

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

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

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

Bericht Nr. / *Report No.* 3521 8285

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

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

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
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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

Bericht Nr. / *Report No.* 3521 8285

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

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

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 Is (steril)
Products of class Is (sterile)

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

Bericht Nr. / *Report No.* 3521 8285

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

M2.98

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

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 Is (steril)
Products of class Is (sterile)

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

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

Bericht Nr. / *Report No.* 3521 8285

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

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

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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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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.* 3521 8285

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

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

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

EC Certificate

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

Registration No.: HD 60131017 0001

Report No.: 15062970 008

Manufacturer:

Jinhua Huacheng Medical
Appliance Co., Ltd.
No. 186 Qingyu Road
Jindong Industrial Park
Jinhua City
321000 Zhejiang
China

Products:

- Disposable Surgical Active Electrodes (Electrosurgical Pencils)
- Disposable Neutral Electrodes
- Disposable Skin Staplers

Replaces Approval, Registration No.: HD 60088776 0001

Expiry Date: 2023-09-17

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: 2018-09-18

Date: 2018-09-05

Notified Body
S. Liu

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®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

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

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

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

Certification Body

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

Date 2018-09-18

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Certifizierungsstelle

X. Ren

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

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

Scope:

Products:

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

Certification Body

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

Date: 2018-09-18

X. Ren

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

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

Scope:

Products:

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

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2018-09-18

X. Ren

ZERTIFIKAT / *Certificate*

DIN EN ISO / EN ISO 13485 : 2016

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

Bıçakcılar Tıbbi Cihazlar Sanayi ve Ticaret A.Ş.

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

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

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

Geltungsbereich / *Scope*

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

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

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

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

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-07-04

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

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

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

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

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

STAUNCHLY MANAGEMENT & SYSTEM SERVICES LTD.
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Email : info@staunchlyservices.com Web : www.staunchlyservices.com