BSS
Better Signal Solution

BSS MEDICAL SUPPLY CO., LIMITED

Document Number : CE-DC-001 Version: A/1

EC Declaration of Conformity

Manufacturer:

BSS MEDICAL SUPPLY CO., LIMITED
No.18, Shabian Road, Torch Hi-tech Industry Zone,
Zhonggshan, China.
info@bssmedical.com

whose single Authorized Representative:

Wellkang Ltd.
Suite B, 29 Harley Street
LONDON, W1G 9QR,U.K.
info@bssmedical.com

We, the manufacturer, herewith declare that the products

Disposable ECG electrode

GMDN Code:11425

meet the provisions of the Council Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

Conformity assessment procedure: Annex VII of Directive 93/43/EEC

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: BSS MEDICAL SUPPLY CO., LIMITED
Address: No.18, Shabian Road Torch Hi-tech Industry Zone, Zhongshan, China.

ZHONGSHAN2018/01/01
Place , date

Harrison Wu
Legally binding signature, Function

18-BEY-01 Adult Electrode LOT: 04192018

EG-Zertifikat / *EC-Certificate*

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

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

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

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

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

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

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

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

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

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-07-04

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

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

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

ANLAGE / *ANNEX*

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

Produkte der Klasse III
Products of class III

Vent Catheter
Atrial Cannula
Vessel Cannula with / without check valve

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

Bericht Nr. / *Report No.* 3521 8285

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

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2018-08-03

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 IIb
Products of class IIb

Pressure Monitoring Set
Lekocyte Filter Set
Gamma Leukocyte Filter Set

Produkte der Klasse IIa
Products of class IIa

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

Bericht Nr. / *Report No.* 3521 8285

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

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ANLAGE / *ANNEX*

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

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

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ZLG-BS-236.10.16

ANLAGE / *ANNEX*

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

Produkte der Klasse IIa
Products of class IIa

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

Bericht Nr. / *Report No.* 3521 8285

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

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

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ZLG-BS-236.10.16

ANLAGE / *ANNEX*

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

Produkte der Klasse 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*

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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
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Essen, 2018-08-03

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

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ANLAGE / *ANNEX*

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

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

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

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

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

Bericht Nr. / *Report No.* 3521 8285

Gültigkeit / *Validity*
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Edition 12

Zertifizierungsstelle für Medizinprodukte
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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

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

ZERTIFIKAT • CERTIFICATE • CERTIFICADO • CERTIFICAT

UNICERT

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Universal GmbH
Certification Services

This certificate is granted to the organization,

HEGELI ORTOPEDIK URUNLER SAN. VE TIC. LTD. STI.

Cihangir Mah. Sehit Piyade Er Yavuz Bahar Sok. No:4 Ambarli Avcilar/ISTANBUL/TURKEY

by review of RA1.004078 numbered report for the scope

MANUFACTURE AND SALES OF ORTHOPEDIC PRODUCTS

to certify that a quality management system in accordance with standard's clauses is established and being implemented

DIN EN ISO 9001:2015

Certificate No : QMS 0115 004134
Original Certification Date : 2015-01-19
Issue / Revised Date : 2017-12-27
Expiry Date : 2019-01-18
Certification Period : 3 years (1st year)

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16058-01-00

Universal GmbH

The authenticity of this certificate can be confirmed online or by e-mail to the Head Office via:
UNIVERSAL GmbH • Wilfried Diekmann Str., 20b, 44536 Lünen Germany • Fon: +49 (0) 231 9931 9960 • info@uni-cert.de • www.uni-cert.de

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Life Medical Equipment
(Guangzhou) Co., Ltd.
5th floor, 13th building Julong
industrial Zone
827 Xicha Road, Baiyun district
Guangzhou
510407 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:	2019-01-16
Certificate Registration No.:	SX 60134524 0001
An audit was performed. Report No.:	17056756 003
This Certificate is valid until:	2021-06-29

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2019-01-16

Herbert Zhong

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

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60134524 0001
Report No.: 17056756 003

Organization:
Life Medical Equipment
(Guangzhou) Co., Ltd.
5th floor, 13th building Julong
industrial Zone
827 Xicha Road, Baiyun district
Guangzhou
510407 Guangdong
China

Scope:

Products:

- Arterial Venous (A.V.) Cannulas
- Tracheobronchial Tube Kits
- Enteral Feeding Tubes
- Enteral Feeding Sets
- Needleless Adapters
- Stopcocks
- IV Infusion Sets
- Extension Sets
- Decompression Pads
- Disinfection Caps
- Heparin Locks
- Urine Bags

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

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2019-01-16

Herbert Zhong

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

Design, Development, Manufacture and Distribution of Disposable Electrosurgical Pencils, Disposable Neutral Electrodes, Physiotherapy Electrodes, Disposable ECG Electrodes, Disposable Skin Staplers

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 60131018 0001
An audit was performed. Report No.:	15062970 008
This Certificate is valid until:	2021-09-17

Certification Body

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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date 2018-09-05

S. Liu

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

TRANSPACIFIC CERTIFICATIONS LIMITED

Certificate of Registration

This is to certify that

Quality Management System

for Medical Devices

of

MEDBAR TIBBİ MALZEMELER TUR. SAN. VE TİC. A.Ş.

FATİH MAHALLESİ 1142 SOKAK NO:35
SARNIÇ - GAZİEMİR - İZMİR / TÜRKİYE.

complies with the requirements of

EN ISO 13485:2012

This certificate is valid concerning all activities related to:

MANUFACTURING AND SALES OF SURGICAL DRAPES, COVERS AND GOWNS HOLDERS, GYNECOLOGY PRODUCTS, PHOTOTHERAPY PRODUCTS, GASTROINTESTINAL PRODUCTS, SURGICAL PRODUCTS AND CRITICAL CARE PRODUCTS.

CERRAHİ KILIFLAR, ÖRTÜ VE ÖNLÜKLER, JİNEKOLOJİ ÜRÜNLERİ, FOTOTERAPİ ÜRÜNLERİ, GASTROİNTESTİNAL ÜRÜNLER, CERRAHİ ÜRÜNLER, YOĞUN BAKIM ÜRÜNLERİ ÜRETİMİ VE SATIŞI.

MD-0884 Certificate No.	Feb. 21, 2018 Date of this Certificate	Feb. 23, 2019 *Next Audit Due Date
Feb. 24, 2017 Date of Initial Registration	Feb. 23, 2020 Certification Expiry Date	Managing Director/Director

JAS-ANZ

TRANSPACIFIC CERTIFICATIONS LIMITED

Website : www.tclcertifications.com E-mail : info@tclcertifications.com
Accreditation by Joint Accreditation System of Australia and New Zealand (Accreditation No.M2640303IN)
4 Phipps Close, DEAKIN, ACT 2600, AUSTRALIA
http://www.jas-anz.org/our-directory/certified-organisations
This certificate is only valid if it is available/valid on TCL website at http://tclcertifications.com/client-register/.
The certificate of Registration remains the property of Transpacific Certifications Limited and shall be returned immediately upon request.
*In case if Surveillance Audit is not allowed to be conducted on or before the specified date; the Certificate shall be Suspended/Withdrawn.

Version 1.00

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

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

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

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

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Certifizierungsstelle

Date 2018-09-18

X. Ren

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

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

Scope:

Products:

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

Certification Body

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

Date: 2018-09-18

X. Ren

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

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

Scope:

Products:

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

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2018-09-18

X. Ren

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

SZUTEST

EC CERTIFICATE

AT SERTİFİKA

According to Annex V of the Directive 93/42/EEC on Medical Devices

93/42/AT Tıbbi Cihaz Yönetmeliği Ek V'e göre

Production Quality Assurance System

Üretim Kalite Güvencesi

Certificate Number: 2195-MED-1816401

Sertifika Numarası

Manufacturer: **R Vent Medikal Üretim A.Ş.**
Üretici *29 Ekim Mah. Balkan Cad. No:33 Torbalı, İzmir, Türkiye*

Product(s):
Ürün(ler)

(1) Steril ve Steril Olmayan Solunum Devre Sistemleri
Sterile and Non-Sterile Breathing Circuit Systems
(2) Steril ve Steril Olmayan Solunum Filtreleri
Sterile and Non-Sterile Breathing Filters
(3) Steril ve Steril Olmayan Katater Bağlantıları
Sterile and Non-Sterile Catheter Mounts

Reference Report No: MM0687-P001-R01, MM0678-P001-R02
Referans Rapor No

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex V, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe and sterile conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex V, Section 4 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s).

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK V bölüm 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen ürünün üretiminin güvenlik ve steril koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK V, bölüm 4'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir.

Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır.

This EC certificate is valid till 2021-06-12.

Bu AT Sertifikası 2021-06-12 tarihine kadar geçerlidir.

Issue Date/*Yayın Tarihi:* 2018-06-13

Mehmet IŞIKLAR
General Manager
Genel Müdür

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Szutest Plaza Nato Yolu Cad. Çam Sok. No:7 Ümraniye 34775 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

SERTİFİKA

Medikal Cihazlar Kalite Yönetim Sistemi

SERTİFİKA NO: 31816401

R Vent Medikal Üretim A.Ş.

29 Ekim Mah. Balkan Cad. No:33 Torbalı, İzmir, TÜRKİYE

EN ISO 13485:2016

Steril ve Steril Olmayan Tek Kullanımlık Solunum Sistemleri Üretimi ve Dağıtımı

Medikal Cihazlar Kalite Yönetim Sistemine yukarıda belirtilen kapsam dahilinde sahip olduğunu onaylar.

Yayın Tarihi	13.06.2018
Geçerlilik Tarihi	12.06.2021
Revizyon Tarih/No	28.01.2019 / 1

TÜRKAK BDS NO YS-B79A-A8B2

TÜRKAK
Tıbbi Cihazlar K Y S
TS EN ISO/IEC 17021
AB-0044-YS

Genel Müdür Yardımcısı

Bu belgenin doğrulanması belge üzerinde bulunan karekodların mobil cihazlara okutulması, http://public.szutest.com.tr adresinde gerekli bilgilerin girilmesi veya BDS no kullanılarak https://tbds.turkak.org.tr adresinden gerçekleştirilebilir.

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 31816401

R Vent Medikal Üretim A.Ş.

29 Ekim Mah. Balkan Cad. No:33 Torbalı, İzmir, TÜRKİYE

EN ISO 13485:2016

Manufacturing and Distribution of Sterile and Non Sterile Disposable Breathing Systems

Approves that the Medical Devices Quality Management System implemented for above scope.

Issue Date	13.06.2018
Expiry Date	12.06.2021
Revision Date/No	28.01.2019 / 1

TÜRKAK BDS NO
YS-B79A-A8B2

TÜRKAK
Tıbbi Cihazlar K. Y. S.
TS EN ISO/IEC 17021
AB-0044-YS

Deputy General Manager

The certificate inquiry is made by reading the QR codes by mobile devices, providing necessary information on http://public.szutest.com.tr or by using BDS No on https://tdbs.turkak.org.tr.

№ 09228
23 Temmuz 2018

EC CERTIFICATE

for the Quality Assurance System

DOCUMENT MARKED AND
IDENTIFIED IN PENANG
MALAYSIA BY:

17/11/17

TAN GAIK CHOON
NOTARY PUBLIC
1st Floor, 46, Rangoon Road
10400 Penang, Malaysia

according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Teleflex Medical Sdn. Bhd.

Lot PT 2577, Jalan Perusahaan 4, 34600 Kamunting Perak, Malaysia

Certified location:

Lot PT 2577, Jalan Perusahaan 4, 34600 Kamunting Perak, Malaysia

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50076-Z6-00, the decision dated 2017-04-19 and is only valid in connection with the successful performance of the annual surveillance audits

This certificate is valid from 2017-06-27 to 2020-06-26

Registration No.: 50076-16-07

ASLINDAN TERCÜMESİ YAPILMISTIR

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-295.10.02

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart, 2017-04-19
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

MÜSTENNATTIR
TEKRARINA
KULLANILAMAZ.

KADIKÖY 13. NOTERI
NAZIK ASKER
BASKATIP
NURTEN ÇAKIR

Annex to the EC Certificate No. 50076-16-07

Revision status: 1

Valid from 2017-06-27 to 2020-06-26

№09228

23 Temmuz 2018

Devices/device categories included in the certificate:

Class II a:

Urology Device

- Foley/Haematuria Catheter (Latex)
- Foley / Haematuria Catheter (PVC)
- Preconnected Urological System (Latex)
- Hyperthermia Bladder Silicone Catheter
- Ureteral Connector
- Catheterization Set
- Suprapubic Catheter (PVC)
- Urodynamic Catheter
- Hydrostatic Catheter
- Silicone Catheter for Radiological Display of Urethra

Respiratory Device

- Breathing Circuits
  - Catheter Mount
  - Heat and Moisture Exchanger
  - Bacterial / Viral Filter
  - HME with Filter
  - Rebreathing bag
  - Multifit Nebuliser System
- Nasal Cannula Set
- Endotracheal Tube (with/without Stylet)

Gastrointestinal Device

- Gastrointestinal Tube
- Intestinal Decompression Tube
- Rectal Tube
- Sengstaken

Gynaecological Device

- Word Catheter

Surgical Device

- Surgical Drainage Tube
- Gas Filter

ASLINDAN TERCÜMESİ YAPILMIŞTIR

MÜSTEDNATTIR. TEK BAŞINA KULLANILMAZ.

KADIKÖY 13. NOTERİ NAZİK AKSOY BAŞKATİP NURTEN ÇAKIR

Annex to the EC Certificate No. 50076-16-07

Revision status: 1

Valid from 2017-06-27 to 2020-06-26

№09228

23 Temmuz 2018

Devices/device categories included in the certificate:

Class II b:

Urology Device

- Foley Catheter (Silicone)
- Latex Foley Catheter (Hydrogel coated)
- Preconnected Urological System (Silicone)
- Suprapubic Catheter (Silicone)
- 2 Way All Silicone Temperature Sensor Catheter
- Silicone Nephrostomy Catheter

Respiratory Device

- Tracheostomy tube and Accessories

TAN GAIK CHOON NOTARY PUBLIC PENANG MALAYSIA

MÜSTECNATTIR. TERCÜMESİ KULAZ.

ASLINDAN TERCÜMESİ YAPILMIŞTİR

DEKRA Certification GmbH Stuttgart Handwerkstraße 15

DEKRA

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2017-10-05
Notified Body ID-number: 0124

KADIKÖY 13. NOTERLİĞİ BAŞKATİP NURTEN CANDAN

T.C.
KADIKÖY 13. NOTERLİĞİ
Rıhtım Cd. Sevket Bey Işhanı
No:12/2 Kadıköy-İstanbul
Tel: 345 64 85 - 418 13 48
Fax: 338 48 13

TERCÜME 23 Temmuz 2018 № 09228

BELGE MALEZYA, PENANG'DA
AŞAĞIDAKİ NOTER TARAFINDAN
MÜHÜRLENMİŞ VE UYGUNLUĞU ONAYLANMIŞTIR:
(Noterin İmzası) 17/11/17
TAN GAIK CHOON
NOTER
1st Floor, 46, Rangoon Road
10400 Penang, Malezya

ASLI GİBİDİR

DEKRA

EC SERTİFİKASI

Direktif 93/42/EEC, Ek II'ye uygun olarak, bölüm (4) hariç Kalite Güvence Sistemi için

Avrupa Birliği Yetkili Kurumu olarak, DEKRA Certification GmbH, işbu belge ile aşağıda belirtilen şirketin

ECE TERCÜME BÜROSU
Tel: 0216 330 92 57-550 47 37
www.ecetercume.com.tr
tercume.ece@gmail.com
Translation Office
Fax: 0216 348 41 86
NOTER YEMİNLİ

Teleflex Medical Sdn. Bhd.

Lot PT 2577, Jalan Perusahaan 4, 34600 Kamunting Perak, Malezya

Onaylı adresi:

Lot PT 2577, Jalan Perusahaan 4, 34600 Kamunting Perak, Malezya

(PENANG, MALEZYA NOTERİ
TAN GAIK CHOON'UN
SOĞUK DAMGASI)

93/42/EEC sayılı direktifin ek II'sine uygun olarak ilişikte listelenmiş bulunan medikal cihazlar için bir kalite güvence sistemi uygulamakta olduğunu tasdik eder. Bu onay 50076-Z6-00 numaralı tekrar sertifikasyon denetim raporu, 19-04-2017 tarihli karar sonuçlarına dayanmaktadır ve sadece yıllık değerlendirme denetimlerinde başarılı performans ile bağlantılı olarak geçerlidir.

İşbu sertifika 27-06-2017 tarihinden 26-06-2020 tarihine kadar geçerlidir.

Tescil No: 50076-16-07

(Dekra kaşesi)

(İmza)
Ruth Delbeck-Bayer
DEKRA Certification GmbH;
Stuttgart, 19-04-2017

Yetkili Kurum No: 0124

ZLG

Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimittlein und
Medizinprodukten
tarafından
görevlendirilmiştir.
ZLG-BS-295.10.02

ECE
Tercüme Bürosu
Translation - Übersetzung - Traduction
Rıhtım Cad. Bıçakçı Sk. Bayraklar Han
Tel: 348 20 18 Fax: 348 41 86
Kadıköy V.D. Vergi No: 2335134 2548

T.C.
KADIKÖY 13. NOTERİ
NOTER YAKIP

№09228

23 Temmuz 2018

50076-16-07 numaralı EC Sertifikasına Ek

Revizyon Durumu: 1

27-06-2017 tarihinden 26-06-2020 tarihine kadar geçerli

Sertifikaya dahil olan ürünler/ürün kategorisi:

Sınıf II a:

Üroloji Ürünleri

- Foley/Hematüri Kateter (Lateks)
- Foley/ Hematüri Kateter (PVC)
- Ön Bağlantılı Ürolojik Sistem (Lateks)
- Hipertermi Mesane Silikon Kateteri
- Üreteral Konnektör
- Katheterizasyon Seti
- Suprapubik Kateter (PVC)
- Ürodinamik Kateter
- Hidrostatik Kateter
- Üretra Radyolojik Görüntüleme için Silikon Kateter

Solunumla ilgili Ürünler

- Solunum Devreleri
  - Kateter Mount
  - Isı ve Nem Değiştirici
  - Bakteriyel / Viral Filtre
  - Filtreli HME
  - Solunum Torbası
  - Multifit Nebülizatör Sistemi
- Nazal Kanül Seti
- Endotrakeal Tüp (Stileli/Stilesiz)

Sindirim Sistemi Ürünleri

- Gastrointestinal Tüp
- Intestinal Dekompresyon Tüpü
- Rektal Tüp
- Sengstaken

Jinekoloji Ürünleri

- Word Kateter

Cerrahi Ürünler

- Cerrahi Drenaj Tüpü
- Gaz Filtresi

(PENANG, MALEZYA NOTERİ
TAN GAIK CHOON'UN
MÜHRÜ VE PARAFI)

№09228

23 Temmuz 2018

50076-16-07 numaralı EC Sertifikasına Ek

Revizyon Durumu: 1

27-06-2017 tarihinden 26-06-2020 tarihine kadar geçerli

Sertifikaya dahil olan ürünler/ürün kategorisi:

Sınıf II b:

Üroloji Ürünleri

- Foley Kateter (Silikon)
- Lateks Foley Kateter (Hidrojel Kaplı)
- Ön Bağlantılı Ürolojik Sistem (Silikon)
- Suprapubik Kateter (Silikon)
- 2 Yollu Tam Silikon Sıcaklık Sensör Kateteri
- Silikon Nefrostomi Kateteri

Solunumla ilgili Ürünler

- Trakeostomi Tüpü ve Aksesuarları

(PENANG, MALEZYA NOTERİ
TAN GAIK CHOON'UN
MÜHRÜ VE PARAFI)

(İmza)
Ruth Delbeck-Bayer
DEKRA Certification GmbH;
Stuttgart, 05-10-2017
Yetkili Kurum No: 0124

SERTİFİKA

Tam Kalite Güvence Sistemi

93/42/AT Tıbbi Cihazlar Direktifi Ek II

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

Ürünler :
- Fototerapi Göz Bandı - Sınıf Is
- Endoskopi Ağızlığı - Sınıf Is
- Pouch Açacağı - Sınıf Is
- Smear Fırçası - Sınıf Is
- Rimel Tipi Smear Fırçası - Sınıf Is
- Smear Spatül - Sınıf Is
- El Ayak Sabitleyici - Sınıf Is
- Trakeostomi Sabitleyici - Sınıf Is
- Endotrakeal Tüp Sabitleyici - Sınıf Is
- Jinekolojik Toplayıcı - Sınıf Is
- İnseminasyon Kanülü - Sınıf Is
- Cerrahi Örtü, Kılıf ve Önlükler - Sınıf Is
- Mikroskop Kılıfı - Sınıf Is
- Video Kamera Kılıfı - Sınıf Is
- Çemberli Kamera Kılıfı - Sınıf Is
- Kartonlu Kamera Kılıfı - Sınıf Is
- Göbek Klempi - Sınıf Is
- Valfli İdrar Torbası - Sınıf Im
- Valfli Kusmuk Torbası - Sınıf Im
- Mide Yıkama Seti - Sınıf Im
- Karmen Kanül Enjektör (Manuel Vakum Aspiratörü) - Sınıf IIa
- Karmen Kanül - Sınıf IIa
- Artroskopi Seti - Sınıf IIa
- Mukus Toplama Kabı - Sınıf IIa
- Damla Ayar Seti - Sınıf IIa
- Cilt İşaretleme Seti - Sınıf IIa
- SFT (Solunum Fonksiyonu Test Cihazı) Filtreli Ağızlık - Sınıf IIa
- Arter Kanül - Sınıf IIa

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 : -
Geçerlilik Tarihi : 02.10.2021

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 05 38814 057

Manufacturer:

Well Lead Medical Co., Ltd.
C-4 Jinhu Industrial Estate, Hualong
511434 Panyu, Guangzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Tracheostomy Tubes, Urethral Catheters, All Silicone Foley Catheters, Foley Catheters with Temperature Sensor, Tracheostomy Tubes with Inner Cannula, Prefilled Syringes with Lubricating Jelly, Foley Catheter Kits, Tracheostomy Tube Kits, Gastrostomy Tubes

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH15080EXT01

Valid from: 2015-09-07
Valid until: 2020-09-06

673086

Date, 2015-06-15

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 05 38814 057

Facility(ies):

Well Lead Medical Co., Ltd.
C-4 Jinhu Industrial Estate, Hualong, 511434 Panyu, Guangzhou, PEOPLE'S REPUBLIC OF CHINA

Well Lead Medical Co., Ltd.
No 47 Guomao Avenue South, 511434 Panyu, Guangzhou, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 15 05 38814 058

Manufacturer:

Well Lead Medical Co., Ltd.
C-4 Jinhu Industrial Estate, Hualong
511434 Panyu, Guangzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

For detailed information see attachment

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH15080EXT01

Valid from: 2015-08-24
Valid until: 2020-08-23

673087

Date, 2015-06-15

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Attachment for Certificate No G2 15 05 38814 058

Supplement 001 dated 2015-06-15

Product Service

For the product(s)/product category (ies):

Urethral Catheters and Tracheal Tubes, Nelaton Catheters, Connecting Tubes with Yankauer Handle, Intubating Stylets, Laryngeal Mask Devices, Tracheobronchial Tubes, Reinforced Endotracheal Tubes, Nebulizers, Oxygen Masks, Non-Rebreath Masks, Tracheostomy Masks, Aerosol Masks, Multi-vent Masks, Endotracheal Tube Introducers, Nasal Oxygen Cannulas, Stylets, Disposable Air Cushion Face Masks, Endotracheal Tube Kits, HMEF(Heat and Moisture Exchanger Filters), Manual Resuscitators, Drainage Systems, Oxygen Catheters, Silicone Tubes, Endobronchial Blocker Tubes, Extraction Bags(Operation Use), Ureteral Stent Sets, Silicone Drainage Systems, Endotracheal Tubes with Evacuation Lumen, Suction Catheters, Feeding Tubes, Stomach Tubes, Silicone Stomach Tubes, Disposable Self-Catheterization Systems, Capnography CO_2 Sampling Masks, O_2+ CO_2 Sampling Cannulas, Non-invasive Positive Pressure Ventilation Masks, Suction Tubes of Oral Care, Bile T-Tubes, Fecal Management Systems, Self Hydrophilic Catheters, Ureteral Access Sheaths, Ureteral Dilation Balloon Catheters, Extracorporeal Circulation Conduct of Blood Purification Apparatus, Urodynamic Catheters, Rectal Pressure Catheters, Anesthetic Breathing Circuits

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