EC Certificate

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

Registration No.: HD 60139711 0001

Report No.: 17047213 009

Manufacturer:

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

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60101918 0001

Expiry Date: 2024-05-27

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

Effective Date: 2019-08-05

Date: 2019-08-05

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

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

Products:

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

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-08-05

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

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

Aspects of manufacture concerned with securing and maintaining sterile conditions:

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

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® III Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-08-05

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

Gültigkeit / *Validity*
von / *from* 2018-09-17
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Certification body for medical devices

Essen, 2018-08-03

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ANLAGE / *ANNEX*

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

Produkte der Klasse 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

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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

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
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Essen, 2018-08-03

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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

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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 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

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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*
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
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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

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

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

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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

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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

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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

Munich, CRT2, 2015-06-15

Hans-Heiner Junker

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

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