EG-Zertifikat / *EC-Certificate*

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

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

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

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

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

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

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

Reg.-Nr. / *Reg.-No.* 04 232 980886
Bericht Nr. / *Report No.* 3524 7139
3526 6208
3526 6290

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

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2020-04-16

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

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.15

Digitally signed by Cojocaru Vera
Date: 2022.11.21 10:42:21 EET
Reason: MoldSign Signature
Location: Moldova

ANLAGE / *ANNEX*

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

Produkte der Klasse IIb
Products of class IIb

Pressure Monitoring Set
Leukocyte Filter Set
Gamma Leukocyte Filter Set

Produkte der Klasse IIa
Products of class IIa

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

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-25

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 IIa
Products of class IIa

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

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
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ZLG-BS-236.10.16

ANLAGE / *ANNEX*

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

Produkte der Klasse IIa
Products of class IIa

Hydrophilic coated uretheral Catheter
IV Filter Set
Aspirators
Blood Transfusion Set
Rectal Catheter
Umbilical Catheter
Angiographic Kit
B-Soft Kit
Aortic Punch
Gas Sampling Line
External Drainage Set
Vent Catheter
Vessel Cannula
Coronary Artery Retraction Clips

Bericht Nr. / *Report No.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

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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)

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.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

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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 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.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 16

Zertifizierungsstelle für Medizinprodukte
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Essen, 2021-05-25

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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.* 3529 1130

Gültigkeit / *Validity*
von / *from* 2021-05-25
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Essen, 2021-05-25

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www.zlg.de
ZLG-BS-236.10.16

ZERTIFIKAT / *Certificate*

DIN EN ISO / EN ISO 13485 : 2016

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

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

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

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

Geltungsbereich / *Scope*

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

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

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

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-09-16

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

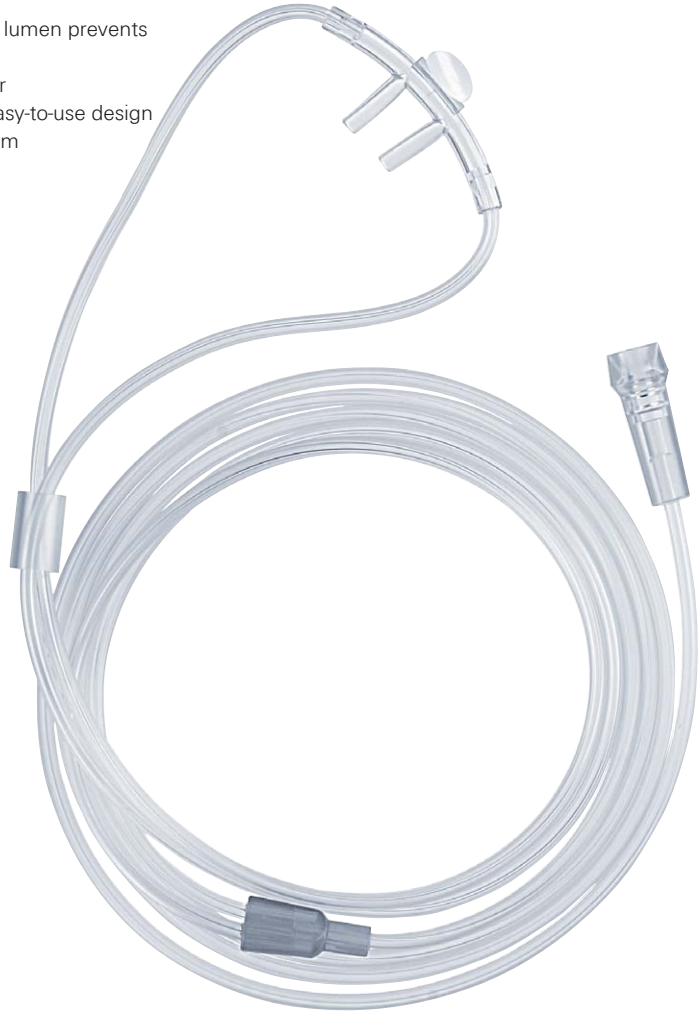
TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

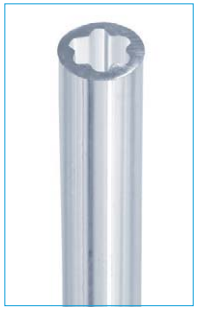
Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

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

Nasal Oxygen Cannula

- Soft and ergonomic nose piece
- Reduced risk of mucosa dehydration
- Flexible, kink resistant, 2.8 x 3.9 mm grooved tubing
- Star shaped tubing lumen prevents kinking
- Standard connector
- Comfortable and easy-to-use design
- Total length: 210 cm



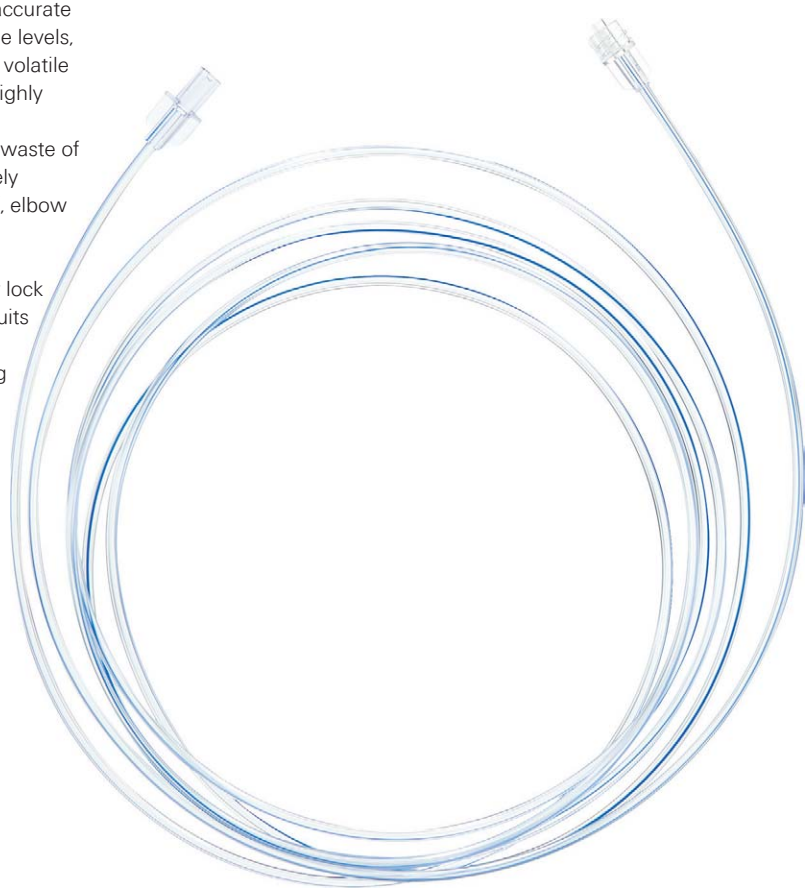


Star Shaped Tubing

Ref
560 2001 2

Gas Sampling Line

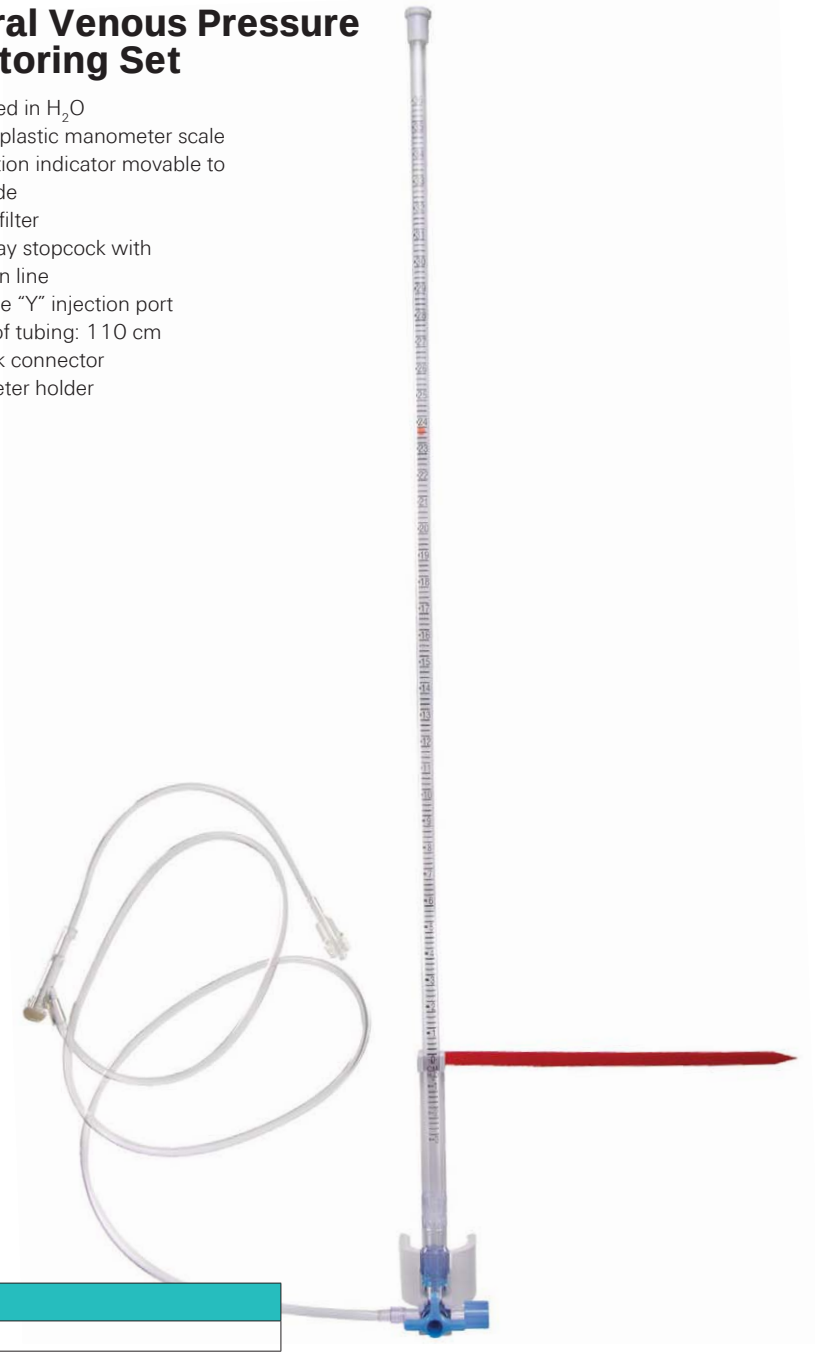
- Monitoring of inspiratory and expiratory gases can give crucial information on a ventilated patient status. In low flow anesthesia in particular, accurate measurement of carbondioxide levels, and inspiratory and expiratory volatile anesthetic concentrations is highly recommended.
- Economic and safe - Prevents waste of anesthetic gases and accurately measures CO_2 level through Y, elbow connector.
- Universal Connection - Most systems use a male/male luer lock configuration. Anesthesia circuits use a female luer lock which requires a male luer lock fitting on the gas line. Male/Male or Female end options.
- Length - The length is dependent on the distance from the point of attachment (anesthesia circuit) to the monitor. We are offering 2 and 3 meter sampling lines.
- Latex-free.



Ref	Connector	Length (m)
573 0071 1	M/F	2
573 0072 1	M/F	3
573 0061 1	M/M	2
573 0062 1	M/M	3

Central Venous Pressure Monitoring Set

- Graduated in H_2O
- Durable plastic manometer scale
- "0" position indicator movable to either side
- Air vent filter
- Three-way stopcock with extension line
- Latex-free "Y" injection port
- Length of tubing: 110 cm
- Luer lock connector
- Manometer holder



Ref
110 0001 1

Instopper

- For intermittent injections through latex-free injection site
- Priming volume 0.088 cc
- Prevents contamination
- Male luer lock
- Color: Yellow

Ref
125 0001 1

Stopper

- For female luer lock connector
- Prevents contamination
- Male luer lock cap
- Color: Ivory

Ref
125 0005 1

Combi Stopper

Female/Male Cap

- For male and female luer lock connectors
- Male and female luer lock cap
- Color: Red

Ref
125 0007 1

Yankauer Suction Set

With Standard and Bulb Tip

- Standard and bulb tip Yankauer suction handle
- 24 Ch (Ø 5.6 x 8.0 mm) kink resistant tubing
- Available in different tubing lengths
- Cut-to-fit and funnel connectors prevents kinking and clogging
- Accepts 6.35 mm (1/4") and 9.50 mm (3/8") connections

Standard Tip

Bulb Tip

Ref			
w/ Standard Tip		w/ Bulb Tip	
Double Pouch	PE Band		
165 2210 1	165 0210 1	164 0210 1	Without Vacuum Control
165 3210 1	165 1210 1	164 1210 1	With Vacuum Control

Yankauer Suction Set

With 20 Ch Tip

- 20 Ch tip Yankauer suction handle
- 24 Ch (Ø 5.6 x 8.0 mm) kink resistant tubing
- Cut-to-fit and funnel connectors prevents kinking and clogging
- Accepts 6.35 mm (1/4") and 9.50 mm (3/8") connections

20 Ch Tip

20 Ch Tip With Four Relieving Eyes

Ref		
w/ 20 Ch Tip	w/ 20 Ch Tip w/ 4 Relieving Eyes	
164 6210 1	164 8210 1	Without Vacuum Control
164 5210 1	164 7210 1	With Vacuum Control

EC Certificate

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

TÜVRheinland®

Registration No.: HD 60144232 0001

Report No.: 17047213 010

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

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60139711 0001

Expiry Date: 2024-05-26

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

Effective Date: 2020-05-26

Date: 2020-05-26

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland III

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

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

Products:

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

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-05-26

Fuxiu Sheng

TÜVRheinland®

Doc. 2/2, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

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

Products:

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

Aspects of manufacture concerned with securing and maintaining sterile conditions:

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

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

Date: 2020-05-26

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2095157-1

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

Scope: Design and Development, Manufacture and Distribution of Disposable Pressure Transducers, Introducer Sets, Guide Wires, Angiographic Syringes, Hemodialysis Catheterization Kits, Patient-Controlled Analgesic Infusion Pumps, Disposable Infusion Pumps, Tracheostomy Tube Kits, Percutaneous Nephrostomy Sets, Ureteral Stent Sets, Drainage Catheter Sets, Transradial Introducer Sets, Introducer Needles, I.V Cannulas, Cervical Ripening Balloon, Postpartum Balloon, Manifolds, Stopcocks, Manifold Sets, Connecting Tubings, Dose-control Syringes, Balloon Inflation Devices, Colored Piston Specialty Syringes, Infusion Sets with Needleless Adapters, Pressure Bandages, Hemostasis Valve Sets, Locking Drainage Catheters, Percutaneous Access Sets, ERCP Guidewires, Injection Caps

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

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

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

Medical Imaging Products Catalogue

Since 1996

Medicath Ltd.

Angiographic Syringes

- Clear body Provides excellent clarification and smooth as glass feelling ,it could see air bubble and contrast medium
- It could be used for computed tomographic scanning, angiography, Nuclear magnetic resonance and imaging
- Great Variety of Syringes, it could match so many injectors

Product No.		Volume(ml)	Description	Models	
Single	Dual		Used for Medrad	Single	Dual
42.16.10000	42.16.10001	200	Used for CT: MCT+ OP-100;VCT610; ECT710	CT-200-A1	CT-200/200-A1
42.16.10002	42.16.10003	200	Used for CT: STELANT	CT-200-A2	CT-200/200-A2
42.16.10004		150	Used for DSA: Mark V & Mark V Provis	DSA-150-A1	
42.16.10005		200	Used for DSA: Mark V & Mark V Provis	DSA-200-A1	
42.16.10007		130	Used for DSA: Mark III & Mark IV	DSA-130-A1	
	42.16.10008	65	Used for MRI: Spectris		MRI-65/65-A1
	42.16.10009	115	Used for MRI: Spectris		MRI-115/115-A1
	42.16.10010	65/115	Used for MRI: Spectris		MRI-65/115-A1
42.16.10011	42.16.10012	190	Used for CT: SALENT	CT-190-A1	CT-190/190-A1
42.16.10016		150	Used for DSA:Mark 7	DSA-150-A2	
	42.16.10019	200	Used for CT STELANT		CT-200/200-A2

Angiographic Syringes

Single

DSA

Dual

Product No.		Volume(ml)	Description	Models	
Single	Dual		Used for Libel-Flarsheim	Single	Dual
42.16.20000	42.16.20001	200	Used for CT: CT 9000 & CT 9000 ADV	CT-200-B1	CT-200/200-B1
42.16.20002		150	Used for DSA: Angiomat 6000	DSA-150-B1	
42.16.20003		150	Used for CT & DSA: Angiomat Illumena	CT/DSA-150-B1	
42.16.20005	42.16.20006	60	Used for MRI: Optistar	MRI-60-B1	MRI-60/60-B1

Product No.		Volume(ml)	Description	Models	
Single	Dual		Used for EZEM	Single	Dual
42.16.50000	42.16.50001	200	Used for CT: Empower	CT-200-EM	CT-200/200-EM

Product No.		Volume(ml)	Description	Models	
Single	Dual		Used for Nemoto Kyorindo	Single	Dual
42.16.30000	42.16.30001	100	Used for CT: A-25	CT-100-NE	CT-100/100-NE
42.16.30002	42.16.30003	200	Used for CT: A-25 A-60	CT-200-NE	CT-200/200-NE
42.16.30005		120	Used for DSA: Nemoto 120S	DSA-120-NE	
42.16.30006	42.16.30007	60	Nemoto Dual Shot. Sonic Shot 50	MRI-60-NE	MRI-60/60-NE
	42.16.30008	100/200	Used for CT:A-25		CT-100/200-NE
	42.16.30012	60/200	Used for CT: A-25,A-60		CT-60/200-NE

Product No.		Volume(ml)	Description	Models	
Single	Dual		Used for Metron	Single	Dual
42.16.40000	42.16.40001	200	Used for CT: ACCUTRON	CT-200-MED	CT-200/200-MED
42.16.40002	42.16.40003	65	Used for MRI: ACCUTRON	MRI-65-MED	MRI-65/65-MED
	42.16.40004	65/200	Used for MRI: ACCUTRON		MRI-65/200-MED

ANGIOGRAPHIC SYRINGE ACCESSORIES

Connecting Tubing(300psI)

Product No.	Description	Length(cm)	ID(mm)	OD(mm)
42.02.90000	Y tube with two check valves	150	1.8	3.6
42.02.90001	Coiled tube	150	1.6	3
42.02.90002	Y tube with two check valves	250	1.8	3.6
42.02.90003	Y tube with one check valve	150	1.8	3.6
42.02.90004	Y tube with one check valve	250	1.8	3.6
42.02.90005	Double infusion line with two check valves	150	2.8	4
42.02.90006	Straight tube	150	1.6	3
42.02.90007	Straight tube	20	1.6	3
42.02.90008	Straight tube with two male check valves	150	1.8	3.6
42.02.90009	Straight tube with two male check valves	250	1.8	3.6
42.02.90010	Coiled tube	150	1.8	3.6
42.02.90011	Straight tube with one needless adapter and spike	25	1.8	3.6
42.02.90012	Y tube with two check valves	15	1.8	3.6
42.02.90013	Coiled tube	50	1.6	3
42.02.90014	Coiled tube	100	1.6	3
42.02.90015	Straight tube with one check valve	12	1.8	3.6
42.02.90016	T tube with one coild tube 150cm and 100cm spike tube	150	1.8	3.6

VENTED SPIKE

Product No.	Length(mm)
42.18.20000	20 ,Bule
42.18.20001	34,Red

“J” Fill Tube

Product No.
42.18.10000

CE

ISO 13485：2012 REGISTERED FIRM

SCW MEDICATH LTD.

Manufacture Add: No.4 Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen 518116, P.R. China

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Version Number：En.A4

Durico C&T, Inc.
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June 4, 2019

DECLARATION OF CONFORMITY

TO WHOM IT MAY CONCERN:

WE, DURICO C&T, INC., HEREBY DECLARE THAT OUR ULSTAR BRAND THERMAL PAPER FOR VIDEO PRINTER (ULSTAR-1100HG, ULSTAR-1100HD, ULSTAR-1100S, ULSTAR-2100HD, ULSTAR-840HG, ULSTAR-840S, ULSTAR-1100HD MATT, ULSTAR-1100HD MIBI, ULSTAR-1100S MIBI) DOESN'T CONTAIN ANY BISPHENOL A .

FOR YOUR INFORMATION, DURICO C&T, INC. IS THE MANUFACTURER AND EXPORTER OF ULSTAR BRAND THERMAL PAPER FOR VIDEO PRINTER (ULSTAR-1100HG, ULSTAR-1100HD, ULSTAR-1100S, ULSTAR-2100HD, ULSTAR-840HG, ULSTAR-840S, ULSTAR-1100HD MATT, ULSTAR-1100HD MIBI, ULSTAR-1100S MIBI).

SINCERELY YOURS,

DURICO C&T, INC.

DURICO C&T, INC. KOREA

H. Chung

AUTHORIZED SIGNATURE

EC Declaration of Conformity

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European representative: Durico Imaging BVBA
Villastraat 2 C
1830 Machelen, Belgium

Product: Thermal Paper for Video Printer (Super ULSTAR Brand)
Model: ULSTAR-1100HG, ULSTAR-1100HD, ULSTAR-2100HD, ULSTAR-1100HD mibi, ULSTAR-1100HD MATT, ULSTAR-1100S, ULSTAR-1100S mibi, ULSTAR-840HG, ULSTAR-840S

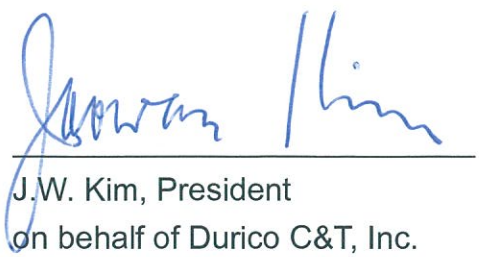
Classification: Class I by the rules of Classification Criteria, Annex IX, MDD 93/42/EEC.

Conformity Assessment Route: Annex VII, MDD 93/42/EEC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Place and Date of issue: Korea, May 1, 2019

Signature:



J.W. Kim, President
on behalf of Durico C&T, Inc.