

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

Registration No.: HD 60144232 0001

Report No.: 17047213 010

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

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60139711 0001

Expiry Date: 2024-05-26

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

Effective Date: 2020-05-26

Date: 2020-05-26

Notified Body



Fuxiu Sheng



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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2 Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60144232 0001
Report No.: 17047213 010

Manufacturer: SCW Medica[®] 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

Date: 2020-05-26

Notified Body



Fuxiu Sheng



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev.0

**Attachment to
Certificate**

Registration No.: HD 60144232 0001
Report No.: 17047213 010

Manufacturer: SCW Medica[®] 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

Date: 2020-05-26

Notified Body



Fuxiu Sheng



G-CERTI *certificate*

hereby certifies that

DURICO C&T INC.

33, Oedap 6-gil, Sangju-si, Gyeongsangbuk-do, Korea

meets the Standard Requirements & Scope as following

ISO 13485:2016

Medical Devices - Quality Management Systems

**Design, Development, Manufacture and Service of Special Paper
(Thermal Paper, Ink-jet Paper, Photographic Paper, Mat Sheet)**

Certificate No : GK-0233-MD
Valid Period : 05 Jul 2021 ~ 04 Jul 2023
Expiry Date : 04 Jul 2023 Issue Date : 05 Jul 2021
Initial Date : 05 Jul 2014

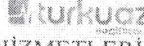
Signed for and on behalf of GCERTI
President I.K.Choi



To verify the validity of this certificate please visit : www.gcerti.com
Korea, Seoul, Eunpyeong-gu, Eunpyeong-ro, 88, 15F. Surveillance
audits shall be conducted at least once a calendar year. Success in
recertification years. This is to certify that the Management Systems
of the client are in conformity with the requirements of the certified
standard. The next certification audit should be conducted by the end of the year.
Reason: MoldSign Signature
Location: Moldova



AB UYGUNLUK BEYANI
AB DECLARATION OF CONFORMITY

Beyanname No Declaration Nu:	DOC-02-0004																																										
Beyanname Tarihi: Declaration Date:	03/09/2021																																										
Üretici: Manufacturer:	 TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ																																										
Münferit Kimlik No / SRN:	N/A																																										
Ürün(ler): Product(s):	NON-STERİL ULTRASON JEL NON-STERILE ULTRASOUND GEL																																										
Temel UDI-DI / BUDI-DI:	868171534101J8																																										
UDI-DI:	<table><tr><td>8698712450293</td><td>20 mL</td></tr><tr><td>8698712457094</td><td>60 mL</td></tr><tr><td>8698712450019</td><td>250 mL</td></tr><tr><td>8681715349572</td><td>250 mL</td></tr><tr><td>8681715349589</td><td>250 mL</td></tr><tr><td>8681715349596</td><td>250 mL</td></tr><tr><td>8681715349602</td><td>250 mL</td></tr><tr><td>8681715349619</td><td>250 mL</td></tr><tr><td>8681715349671</td><td>250 mL</td></tr><tr><td>8681715349626</td><td>250 mL</td></tr><tr><td>8681715349633</td><td>250 mL</td></tr><tr><td>8698712450026</td><td>500 mL</td></tr><tr><td>8681715349947</td><td>500 mL</td></tr><tr><td>8698712450033</td><td>1000 mL</td></tr><tr><td>8683229600514</td><td>1000 mL</td></tr><tr><td>8681715349640</td><td>1000 mL</td></tr><tr><td>8698712450057</td><td>5000 mL</td></tr><tr><td>8681715349664</td><td>5000 mL</td></tr><tr><td>8681715349688</td><td>5000 mL</td></tr><tr><td>8698712450040</td><td>5000 mL (Galon)</td></tr><tr><td>8681715349657</td><td>5000 mL (Galon)</td></tr></table>	8698712450293	20 mL	8698712457094	60 mL	8698712450019	250 mL	8681715349572	250 mL	8681715349589	250 mL	8681715349596	250 mL	8681715349602	250 mL	8681715349619	250 mL	8681715349671	250 mL	8681715349626	250 mL	8681715349633	250 mL	8698712450026	500 mL	8681715349947	500 mL	8698712450033	1000 mL	8683229600514	1000 mL	8681715349640	1000 mL	8698712450057	5000 mL	8681715349664	5000 mL	8681715349688	5000 mL	8698712450040	5000 mL (Galon)	8681715349657	5000 mL (Galon)
8698712450293	20 mL																																										
8698712457094	60 mL																																										
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8681715349572	250 mL																																										
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8698712450040	5000 mL (Galon)																																										
8681715349657	5000 mL (Galon)																																										
UDI-PI:	[(10) LOT / BATCH NO] [(11) ÜRT / PRD DATE] [(17) SKT / EXP DATE]																																										
Referans/Katalog No: Reference/Catalogue Number:	<table><tr><td>NUG-0001</td><td>20 Ml</td></tr><tr><td>SUG-0002</td><td>60 mL</td></tr><tr><td>NUG-0003</td><td>250 mL</td></tr></table>	NUG-0001	20 Ml	SUG-0002	60 mL	NUG-0003	250 mL																																				
NUG-0001	20 Ml																																										
SUG-0002	60 mL																																										
NUG-0003	250 mL																																										

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		NUG-0004	250 mL
		NUG-0005	250 mL
		NUG-0006	250 mL
		NUG-0007	250 mL
		NUG-0008	250 mL
		NUG-0009	250 mL
		NUG-0010	250 mL
		NUG-0011	250 mL
		NUG-0019	500 mL
		NUG-0020	500 mL
		NUG-0012	1000 mL
		NUG-0012	1000 mL
		NUG-0013	1000 mL
		NUG-0016	5000 mL
		NUG-0017	5000 mL
		NUG-0018	5000 mL
		NUG-0014	5000 mL (Galon)
		NUG-0015	5000 mL (Galon)
Versiyon/Model No: Version/Model Number:		Y0000.101.0013	20 mL
		Y0000.101.0039	60 mL
		Y0000.101.0001	250 mL
		Y0000.101.0002	250 mL
		Y0000.101.0003	250 mL
		Y0000.101.0004	250 mL
		Y0000.101.0032	250 mL
		Y0000.101.0059	250 mL
		Y0000.101.0066	250 mL
		Y0000.101.0077	250 mL
		Y0000.101.0062	250 mL
		Y0000.101.0005	500 mL
		Y0000.101.0006	500 mL
		Y0000.101.0016	1000 mL
		Y0000.101.0018	1000 mL
		Y0000.101.0017	1000 mL
		Y0000.101.0011	5000 mL
		Y0000.101.0012	5000 mL

Doküman No / Document No:	TF011.01.00.002	Yayın Tarihi / Release Date:	3.9.2021	Revizyon No / Revision No:	0	Revizyon Tarihi / Revision Date:	3.9.2021	Sayfa No / Page No:	2 / 5
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TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEKNİK KİMYASAL ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ

Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad. No:45/5, 34522, Esenyurt / İstanbul / Türkiye
T: +90 212 428 6848 | F: +90 212 428 6853 | W: www.turkuazsaglik.com.tr | M: info@turkuazsaglik.com.tr

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		Y0000.101.0063	5000 mL
		Y0000.101.0009	5000 mL (Galon)
		Y0000.101.0010	5000 mL (Galon)
Marka: Trademark:	KONIX		
Kullanım Amacı: Intended Use:	Non-Steril Ultrason Jel ultrason uygulamalarında görüntü ve kaydırma amaçlı kullanılır. <i>Non-Sterile Ultrasound Gel is used for ultrasonic imaging and lubrication.</i>		
Ürün Görseli: Product Photo:			

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TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ

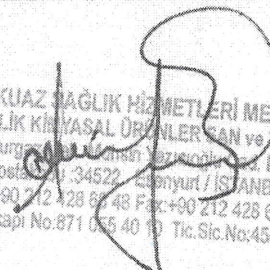
Akcaburgaz Mah. Muhsin Yazıcıoğlu Cad. No:45/5. 34522, Esenyurt / İstanbul / Türkiye
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Ortak Özellikler: <i>Common Specifications:</i>	EN ISO 13485, EN ISO 14971, EN ISO 62366, EN ISO 14644-1, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, EN ISO 15223-1, EN ISO 14698-1, ISO 16142-1, ISO/TR 20416, ISO 20417
GMDN:	15321 Jel, ultrasonik bağlama Bir ultrason inceleme sırasında deri içinden geçen ultrasonik dalgaların alınması ve verilmesi için iyileştirilmiş temas ve şartların sağlandığı bir madde. Ayrıca operatörün probu cilt üzerinde düzgün bir şekilde hareket ettirebilmesine de yardımcı olmaktadır. 15321 Gel, ultrasonic bonding A substance that provides improved contact and conditions for receiving and transmitting ultrasonic waves that pass through the skin during an ultrasound examination. It also helps the operator to move the probe smoothly over the skin.
AB Direktifi ve Mevzuat <i>EU Directive and Legislation:</i>	- 02.06.2021 Tarih 31499 Sayılı Mükerrer Resmi Gazete / Tıbbi Cihaz Yönetmeliği Regulation (EU) 2017/745
Risk Sınıfı: <i>Risk Classification:</i>	Sınıf I, Ek VIII, Kural I Class I, Annex VIII, Rule I
Uygunluk Yolu: <i>Conformity Route:</i>	MDR Ek IV (Ek II ve Ek III) MDR Annex IV (Annex II and Annex III)
Beyan: <i>Declaration:</i>	İşbu AB Uygunluk Beyanı, TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ sorumluluğunda yayınlanmıştır. Beyanda bahse konu tıbbi cihazın, ilgili AB direktifi ve varsa, bir AB Uygunluk beyanı

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	düzenlenmesini sağlayan diğer ilgili AB mevzuatıyla uyumlu olduğu beyan edilmektedir. <i>This EU Declaration of Conformity is issued under the sole responsibility of the TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ. In the declaration, it is declared that the medical device in question is in compliance with the relevant EU directive and, if any, other relevant EU legislation enabling the issuance of an EU Declaration of Conformity.</i>	
Beyan Eden: Declarant:	KYT / QMR Hanifi Karahan Bozkurt Arge ve Kalite Direktörü <i>R&D and Quality Director</i>	 TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SAN. VE TİC.A.Ş. Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad. No:45/5 Posta No: 34522 Esenyurt / İSTANBUL Tel: +90 212 428 68 48 Fax: +90 212 428 68 53 Yenikapı No: 871 055 40 10 Tic. Sic. No: 450836
Beyanın Düzenlenme Yeri: Place of Declaration:	Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad. No:45/5 34522 Esenyurt / İstanbul / Türkiye	
Onaylı Kuruluş: Notified Body:	N/A	
AB Sertifikası: EU Certificate:	N/A	
Tasarım Sertifikası: Design Certificate:	N/A	
Teknik Dosya No ve Saklama Adresi: Technical File Nu and Retention Address:	TF011.01	
AB Yetkili Temsilci: EU Authorized Representative:	N/A	
Ek Bilgi: Additional Information:	Bu uygunluk deklarasyonu ürünlerin pazara arz edildiği tüm ülkelerde, o ülkenin dilinde hazırlanmış kullanım kılavuz ve etiketleriyle ve yetkili ithalatçı veya distribütörünün sorumluluğuyla geçerlidir. <i>This declaration of conformity is valid with labels and IFUs prepared in the local language where the products have been marketed under the responsibility of the authorised importer or distributor.</i>	

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