

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Attachment to  
Certificate

Registration No.: HD 60101918 0001  
Report No.: 17047213 005

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

Date: 2018-09-18



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60130880 0001  
**Report No.:** 17047213 005

**Organization:** SCW Medcath 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**



**Date:** 2018-09-18



# 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



Date 2018-09-18

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
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