

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





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



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



DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-09-18

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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