

Doc. 1/2, Rev. 1

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

Attachment to Certificate

Registration No.: Report No.:

HD 60101918 0001 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

Doc. 2/2, Rev. 0

Attachment to Certificate

Registration No.:

SX 60130880 0001 17047213 005

Report No.:

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** 

DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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

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

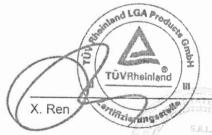
This Certificate is valid until:

2021-07-08 ·

Certification Body

Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Date 2018-09-18



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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