



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

Registration No.: HD 60101918 0001

Report No.: 17047213 001

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

Products: Medical Devices  
(see attachment for products included)  
Replaces Approval, Registration No.: HD 60031292 0001

Expiry Date: 2020-07-08

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: 2015-07-09

Date: 2015-07-09

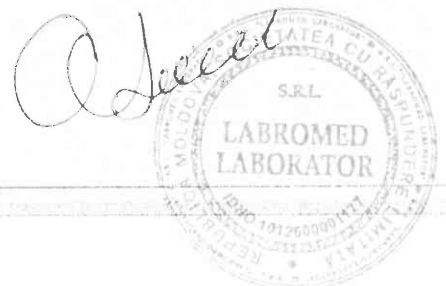


Notified Body

Ren

**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**

Attachment to  
Certificate

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

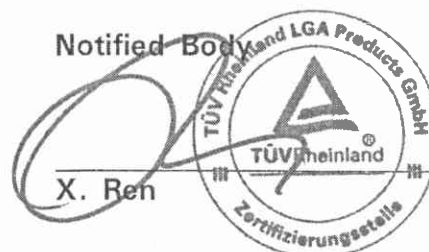
**Manufacturer:** SCW Med cath Ltd.  
No. 4 Baolong 6th Road  
Baolong Industrial Town  
Longgang District, Shenzhen  
518116 Guangdong  
China

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

- Dose-control Syringes
- Manifolds
- Stopcocks
- Balloon Inflation Devices
- Colored Piston Specialty Syringes
- Manifold Sets
- Infusion Sets with Needleless Adapters
- Connecting Tubings
- Pressure Bandages
- Hemostasis Valve Sets

Date: 2018-09-18

Notified Body



**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:**

- Hemostasis Valve Sets
- Disposable Pressure Transducers
- Introducer Sets
- Guide Wires
- Connecting Tubings
- 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

**Certification Body**



Deutsche  
Akkreditierungsstelle  
D-ZM-14169-01-02

**Date:** 2018-09-18

