

**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

X. 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 001

**Manufacturer:** SCW Medica<sup>th</sup> Ltd.  
No. 4 Baolong 6<sup>th</sup> Road  
Baolong Industrial Town  
Longgang District, Shenzhen  
518116 Guangdong  
China

**Products:**

- Hemostasis Valve Sets
- 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

**Date:** 2015-07-09



**Notified Body**

**Xe Ren**

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

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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

**Date:** 2015-07-09



**Notified Body**

**X. Ren**