



Benannt durch/Designated by  
 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
 www.zlg.de  
 ZLG-BS-244.10.08



Product Service

# EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
 (Devices in Class IIa, IIb or III)

**No. G1 104068 0002 Rev. 00**

**Manufacturer:**

**SCW Medicath Ltd.**

No.4, Baolong 6th Road  
 Baolong Industrial Town  
 Longgang District  
 518116 Shenzhen, Guangdong  
 PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies): Hydrophilic Guidewire**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** GZ1942701

**Valid from:** 2020-01-07

**Valid until:** 2024-05-26

**Date,** 2020-01-07

Christoph Dicks  
 Head of Certification/Notified Body

TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ СЕРТИФИКАТ ♦ CERTIFICADO ♦ CERTIFICAT



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**No. G1 104068 0002 Rev. 00**

**Facility(ies):**

SCW Medicath Ltd.  
No.4, Baolong 6th Road, Baolong Industrial Town, Longgang  
District, 518116 Shenzhen, Guangdong, PEOPLE'S REPUBLIC  
OF CHINA



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

**Registration No.:** HD 60144232 0001

**Report No.:** 17047213 010

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

**Products:** Medical Devices  
  
(see attachment for products included)  
  
Replaces Approval, Registration No.: HD 60139711 0001

**Expiry Date:** 2024-05-26

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:** 2020-05-26

**Date:** 2020-05-26

Notified Body

Fuxiu Sheng



**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 60144232 0001  
**Report No.:** 17047213 010

**Manufacturer:** SCW Mediatech Ltd.  
No. 4 Baolong 6th Road  
Baolong Industrial Town  
Longgang District, Shenzhen  
518116 Guangdong  
P.R. 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

**Notified Body**

**Date:** 2020-05-26



**Fuxiu Sheng**



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

**Attachment to  
Certificate**

**Registration No.:** HD 60144232 0001  
**Report No.:** 17047213 010

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

**Products:**

- Locking Drainage Catheters
- Percutaneous Access Sets
- ERCP Guidewires
- Manifolds
- Stopcocks
- Manifold Sets
- Connecting Tubings

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Dose-control Syringes
- Balloon Inflation Devices
- Colored Piston Specialty Syringes
- Infusion Sets with Needleless Adapters
- Pressure Bandages
- Hemostasis Valve Sets
- Injection Caps

**Date:** 2020-05-26

**Notified Body**



**Fuxiu Sheng**



