

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 Med cath 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

Doc. 1/2 Rev. 0

**Attachment to
Certificate**

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

Manufacturer:

SCW Medicaht 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

Doc. 2/2, Rev.0

Attachment to
Certificate
Registration No.:
Report No.:

HD 60144232 0001
17047213 010

Manufacturer:

SCW Medicath 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



Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2095157-1

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

Scope: Design and Development, Manufacture and Distribution of 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, Manifolds, Stopcocks, Manifold Sets, Connecting Tubings, Dose-control Syringes, Balloon Inflation Devices, Colored Piston Specialty Syringes, Infusion Sets with Needleless Adapters, Pressure Bandages, Hemostasis Valve Sets, Locking Drainage Catheters, Percutaneous Access Sets, ERCP Guidewires, Injection Caps

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10918574-100
Effective date: 2021-07-09
Expiry date: 2024-07-08
Issue date: 2021-07-05



Dipl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Deutsche
Akkreditierungsstelle
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