

## **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

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜVRheinlar

Wilzierungsst

Notified Body

Ren

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. 2/2, Rev. 1

Attachment to Certificate

Registration No.:

HD 60101918 0001

Report No.:

17047213 005

Manufacturer:

SCW Medicath 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 and LGA Products

TÜVI meinland

X. Ren

Türi meinland

S.R.L.
LABROMED
LABORATOR



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

Doc. 1/2, Rev. 0

Attachment to Certificate

Registration No.:
Report No.:

SX 60130880 0001

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

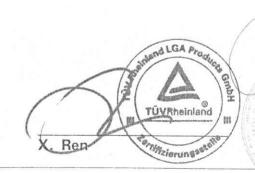
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**Certification Body** 

DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2018-09-18



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