EC Certificate

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

TÜVRheinland®

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 Zertifizierungsstelle

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.

Digitally signed by Cojocaru Vera
Date: 2024.03.13 07:26:38 EET
Reason: MoldSign Signature
Location: Moldova

TÜVRheinland®

Doc. 1/2 Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
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:

- 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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-05-26

Fuxiu Sheng

TÜVRheinland®

Doc. 2/2, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
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:

- 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

Notified Body

Fuxiu Sheng

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-05-26

Certificate

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

EC Declaration of Conformity

Manufacturer:	*whose single Authorized Representative:*
SCW MEDICATH LTD.	**OBELIS S.A.**
NO.4, Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, 518116, Guangdong, P.R. China	Bd. Général Wahis 53 1030 Brussels, Belgium

We, the manufacturer, herewith declare that the products

Balloon Inflation Devices

Models: SCW-BID-20, SCW-BID1-20, SCW-BID1-30, SCW-BID2-20

GMDN Code: 17541

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class Is according to Annex IX Rule 2 of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland

Certificate No.: HD 60144232 0001
Issue date: 26.05.2020
Expiry date: 26.05.2024

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

For Class Is product only: Application of the abovementioned Annexes and the intervention by the Notified Body is limited to: the aspects of manufacture concerned with securing and maintaining sterile conditions.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

SCW MEDICATH LTD.
NO.4, Baolong 6th Road, Baolong Industrial Town,
Longgang District, Shenzhen, 518116, Guangdong, P.R. China

Shenzhen, 2022/09/21
Place, date

Miriam Xie
Legally binding signature, Function