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

Digitally signed by Cojocaru Vera
Date: 2024.06.04 13:20:02 EEST
Reason: MoldSign Signature
Location: Moldova

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.

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

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

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

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date April 02, 2024

Notified Body Confirmation Letter
Reference. : 10924200

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

SCW Medicath Ltd.
No.4, Baolong 6th Road,
Baolong Industrial Town,
Longgang District, Shenzhen,
518116 Guangdong,
P.R. China
SRN Number (if available): CN-MF-000019140

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland
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The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Samuel QIN

Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Postpartum Balloon **Basic UDI-DI: 6938820500000000000006027**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Postpartum Balloon **Basic UDI-DI: 693882050000000000000362A**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Cervical Ripening Balloon **Basic UDI-DI: 6938820500000000000006129**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Cervical Ripening Balloon **Basic UDI-DI: 693882050000000000000372C**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Guide Wire **Basic UDI-DI:** **6938820500000000000013ZT**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Hemostasis Valve Sets **Basic UDI-DI:** **6938820500000000000012ZR**	Class I devices placed on the market in sterile condition	N/A	Certificate # HD 60144232 0001 NB #0197
Stopcock **Basic UDI-DI:** **6938820500000000000014ZV**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Balloon Inflation Device **Basic UDI-DI:** **6938820500000000000002ZN**	Class I devices placed on the market in sterile condition	N/A	Certificate # HD 60144232 0001 NB #0197
Connecting Tubing **Basic UDI-DI:** **6938820500000000000004ZS**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Manifold **Basic UDI-DI:** **6938820500000000000001828**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Pressure Bandage **Basic UDI-DI:** **6938820500000000000006ZW**	Class I devices placed on the market in sterile condition	N/A	Certificate # HD 60144232 0001 NB #0197
Colored piston specialty Syringe **Basic UDI-DI:** **6938820500000000000022ZU**	Class I devices placed on the market in sterile condition	N/A	Certificate # HD 60144232 0001 NB #0197
Dose-control Syringe **Basic UDI-DI:** **6938820500000000000020ZQ**	Class I devices placed on the market in sterile condition	N/A	Certificate # HD 60144232 0001 NB #0197
Manifold Set **Basic UDI-DI:** **6938820500000000000002729**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Ureteral Stent Set **Basic UDI-DI: 6938820500000000000031ZV**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Tracheostomy Tube Kits **Basic UDI-DI: 6938820500000000000292D**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Tracheostomy Tube Kits **Basic UDI-DI: 6938820500000000000622B**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Tracheostomy Tube Kits **Basic UDI-DI: 6938820500000000000632D**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Percutaneous Nephrostomy Sets **Basic UDI-DI: 6938820500000000000282B**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Locking Drainage Catheter **Basic UDI-DI: 6938820500000000000392G**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
ERCP Guidewire **Basic UDI-DI: 6938820500000000000040ZW**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Percutaneous Access Set **Basic UDI-DI: 6938820500000000000382E**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Infusion Sets with needleless adapter **Basic UDI-DI: 6938820500000000000002525**	Class I devices placed on the market in sterile condition	N/A	Certificate # HD 60144232 0001 NB #0197
Drainage Catheter Sets **Basic UDI-DI: 6938820500000000000023ZW**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Introducer Needles **Basic UDI-DI: 6938820500000000000002627**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Introducer Sets **Basic UDI-DI: 6938820500000000000011ZP**	Class IIa	N/A	Certificate # HD 601442320001 NB #0197
Transradial Introducer Sets **Basic UDI-DI: 6938820500000000000030ZT**	Class IIa	N/A	Certificate # HD 601442320001 NB #0197
Hemodialysis Catheterization Kit **Basic UDI-DI: 6938820500000000000021ZS**	Class IIa	N/A	Certificate # HD 601442320001 NB #0197
Hemodialysis Catheterization Kit **Basic UDI-DI: 6938820500000000000662K**	Class IIa	N/A	Certificate # HD 601442320001 NB #0197
Hemodialysis Catheterization Kit **Basic UDI-DI: 6938820500000000000672M**	Class IIa	N/A	Certificate # HD 601442320001 NB #0197
Angiographic Syringes **Basic UDI-DI: 6938820500000000000001ZL**	Class IIa	N/A	Certificate # HD 601442320001 NB #0197
Disposable Infusion Pumps **Basic UDI-DI: 6938820500000000000652H**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 601442320001 NB #0197
Patient-Controlled Analgesic Infusion Pumps **Basic UDI-DI: 6938820500000000000642F**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 601442320001 NB #0197
Disposable Pressure Transducers **Basic UDI-DI: 6938820500000000000192A**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 601442320001 NB #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
I.V Cannulas **Basic UDI-DI: 6938820500000000000002423**	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Injection Cap **Basic UDI-DI: 6938820500000000000592N**	Class I devices placed on the market in sterile condition	N/A	Certificate # HD 60144232 0001 NB #0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/02	SCWME_CL607_2024-04-02	Initial issue