

TÜV Rheinland LGA Products GmbH • 51105 Köln

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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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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.

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Supervisory Board

Dr.-Ing. Michael Fübi

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: 6938820500000000000000362A	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Cervical Ripening Balloon Basic UDI-DI: 69388205000000000000006129	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Cervical Ripening Balloon Basic UDI-DI: 6938820500000000000000372C	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: 693882050000000000000013ZT	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Hemostasis Valve Sets Basic UDI-DI: 693882050000000000000012ZR	Class I devices placed on the market in sterile condition	N/A	Certificate # HD 60144232 0001 NB #0197
Stopcock Basic UDI-DI: 693882050000000000000014ZV	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Balloon Inflation Device Basic UDI-DI: 693882050000000000000002ZN	Class I devices placed on the market in sterile condition	N/A	Certificate # HD 60144232 0001 NB #0197
Connecting Tubing Basic UDI-DI: 693882050000000000000004ZS	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Manifold Basic UDI-DI: 69388205000000000000001828	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Pressure Bandage Basic UDI-DI: 693882050000000000000006ZW	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: 693882050000000000000002ZU	Class I devices placed on the market in sterile condition	N/A	Certificate # HD 60144232 0001 NB #0197
Dose-control Syringe Basic UDI-DI: 6938820500000000000000020ZQ	Class I devices placed on the market in sterile condition	N/A	Certificate # HD 60144232 0001 NB #0197
Manifold Set Basic UDI-DI: 693882050000000000000002729	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: 69388205000000000000031ZV	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Tracheostomy Tube Kits Basic UDI-DI: 693882050000000000000292D	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Tracheostomy Tube Kits Basic UDI-DI: 693882050000000000000622B	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Tracheostomy Tube Kits Basic UDI-DI: 693882050000000000000632D	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Percutaneous Nephrostomy Sets Basic UDI-DI: 693882050000000000000282B	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Locking Drainage Catheter Basic UDI-DI: 693882050000000000000392G	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
ERCP Guidewire Basic UDI-DI: 69388205000000000000040ZW	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Percutaneous Access Set Basic UDI-DI: 693882050000000000000382E	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Infusion Sets with needleless adapter Basic UDI-DI: 693882050000000000000252S	Class I devices placed on the market in sterile condition	N/A	Certificate # HD 60144232 0001 NB #0197
Drainage Catheter Sets Basic UDI-DI: 69388205000000000000023ZW	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 60144232 0001 NB #0197
Transradial Introducer Sets Basic UDI-DI: 69388205000000000000030ZT	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Hemodialysis Catheterization Kit Basic UDI-DI: 693882050000000000000021ZS	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Hemodialysis Catheterization Kit Basic UDI-DI: 6938820500000000000000662K	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Hemodialysis Catheterization Kit Basic UDI-DI: 6938820500000000000000672M	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Angiographic Syringes Basic UDI-DI: 693882050000000000000001ZL	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Disposable Infusion Pumps Basic UDI-DI: 6938820500000000000000652H	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60144232 0001 NB #0197
Patient-Controlled Analgesic Infusion Pumps Basic UDI-DI: 6938820500000000000000642F	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60144232 0001 NB #0197
Disposable Pressure Transducers Basic UDI-DI: 6938820500000000000000192A	Class IIb excluding Class IIb implantable non-WET	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
I.V Cannulas Basic UDI-DI: 69388205000000000000002423	Class IIa	N/A	Certificate # HD 60144232 0001 NB #0197
Injection Cap Basic UDI-DI: 6938820500000000000000592N	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 NOT 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