Obelis Swiss GmbH

Registered Address
Ruessenstrasse 12
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Switzerland

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SWISS AUTHORIZED REPRESENTATIVE CERTIFICATE

(Article 51 of the Medical device ordinance of 1 July 2020 (MedDO) SR 812.213)

Date: 17/01/2024

Reference No.: CH PDN 0106-2024

Order No.: CH MD 0037-2023

Manufacturer:
SCW MEDICATH LTD.
No.4 Baolong 6th Road,
Baolong Industrial Town,
Longgang District, Shenzhen 518116
P.R. China

Facilities:
SCW MEDICATH LTD.
No.4 Baolong 6th Road,
Baolong Industrial Town,
Longgang District, Shenzhen 518116
P.R. China

Product Categories: Please See Annex A - List of Devices (4 Devices, 3 Pages)

Models: Please See Annex A - List of Devices (4 Devices, 3 Pages)

Obelis Swiss GmbH confirms hereby that it has been designated by the above mentioned manufacturer as Authorized Representative in Switzerland in accordance with Article 51 paragraph 1 and 3 of the Medical Device Ordinance of 1 July 2020 (MedDO SR.812.213), referring to Art.11 of the MDR (EU) 2017/745, provided that the manufacturer complied with the terms and conditions set out in the CH-REP Services Agreement which entered into force on **01/07/2023** and with the mandate signed by both parties on **05/12/2023** related to the devices listed in the Annex A.

SWISS AUTHORIZED REPRESENTATIVE OBELIS SWISS GMBH

G. ELKAYAM CEO

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Mr. G. Elkayam CEO

Obelis Swiss GmbH

*This certificate is not a confirmation of product notification nor an approval to place products on the market.
**This certificate will become void automatically upon termination of the CH REP Agreement or rejection of the products from Obelis Swiss GmbH PRRC.

ANNEX to Swiss Authorized Representative Certificate

Order No.: EU MD 0037-2023

Reference No.: CH PDN 0106-2024

Manufacturer: SCW MEDICATH LTD.

Country: P.R. China

#	GMDN/ EMDN	Generic device name (including BASIC UDI)	Commercial Name of device	Intended use	Class	Rule	Legacy (Y/N)	Mandated (Y/N)	Mandate starting date	Mandated Vigilance (Y/N)
1	58865/ C0504	**TRANSRADIAL INTRODUCER SETS** 6938820500000 0000000030ZT	TRANSRADIAL INTRODUCER SETS	The transradial introducer set is designed for the Introduction of balloon, diagnostic and guiding catheters or other devices for diagnosis and Intervention in radial artery access procedures.	Class IIa	Rule 6	Y	Y	05/12/2023	Y
2	15286/ Z11039013	**ANGIOGRAPHIC SYRINGES** 6938820 5000000	ANGIOGRAPHIC SYRINGES	Angiographic syringe is intended to deliver contrast media, which is	Class IIa	Rule 2	Y	Y	05/12/2023	Y

				compatible with high pressure injection equipment during CT, DSA and MRI.						
3	15286/ Z11039013	**POSTPARTUM BALLOON** 693882050000000000000362A	POSTPARTUM BALLOON	The Postpartum Balloon is a silicone balloon catheter with a maximum inflation volume of 500 mL. The Rapid Instillation Components include polymer tubing with an IV bag spike and three-way valve.	Class IIa	Rule 7	Y	Y	05/12/2023	Y
4	47126/ Z12080299	**CERVICAL RIPENING BALLOON** 693882050000000000000372C	CERVICAL RIPENING BALLOON	The Cervical Ripening Balloon is a silicone double balloon catheter. Maximum balloon inflation is 80mL/balloon.	Class IIa	Rule 5	Y	Y	05/12/2023	Y

Date **17/01/2024**

Stamp

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