Obelis Swiss GmbH

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CERTIFICATE OF LEGACY DEVICE

Reference No.: CH PDN 0107-2024 **Date:** 17/01/2024

Order No.: CH MD 0037-2023

This is to certify that Obelis Swiss GmbH maintains a copy of the technical documentation related to the devices mentioned below including key procedures of the manufacturer's quality management system. Obelis Swiss GmbH has verified that the following manufacturer complies with the Articles of the Medical Device Ordinance of 1 July 2020 (MedDO, SR 812.213) related to registration of economic operators and devices, post-market surveillance and vigilance:

Name: SCW MEDICATH LTD.

Address: No.4 Baolong 6th Road, Baolong Industrial Town
Longgang District,
Shenzhen 518116, P.R. China

The devices mentioned below fall under the scope of Art.101 MedDO and of Article 120.3a MDR:

✔ Devices which have a certificate issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC prior to 26 May 2021 and for which the manufacturer declares compliance with Article 120.2 MDR. (Article 120.3a)

Devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to MDR requires the involvement of a notified body. (Article 120.3b)

By way of derogation to Article 5 of the MDR and Art.6 MedDO, those devices may be placed on the market or put into service until the dates indecated in the attached Annex A provided that the conditions of MedDO Art.101.2 and those of MDR Articles 120.3c and 120.3d are complied with.

The application of Article 120.3 MDR and of Art.101 MedDO becomes void in case the manufacturer and/or the devices cease to comply with any of the conditions mentioned in MDR Articles 120.3c and 120.3d.

DEVICES NAME AND DESCRIPTION: PLEASE SEE ANNEX A - LIST OF EQUIPMENTS (1 PAGE, 4 DEVICES)

The Manufacturer may place these devices on the Swiss territory with Obelis Swiss GmbH as Swiss Authorized Representative.

SWISS AUTHORIZED REPRESENTATIVE OBELIS SWISS GMBH

G. ELKAYAM CEO

Obelis Swiss Gmbh
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6340 Baar,Switzerland
Tel:+41 41 544 15 26
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Mr. G. Elkayam CEO

Obelis Swiss GmbH

**This certificate will become void automatically if the product is rejected by the Swiss Authorities, Obelis Swiss GmbH PRRC or upon termination of the CH REP agreement.
***This Certificate does not certify that the devices listed in Annex A comply with the Essential requirements of MDD or AIMD.

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Annex A - List of Devices

(Medical Device Ordinance, MedDO SR 812.213)

#	Commercial Name	Short description and intended use	How device is placed on market from 26 May 2021	Is the device an MD-DEVIT product as per definition of Art.1(3) lett.c.2 and lett.d MedDO?	Does the product contain a medicinal product as per definition of Art.4.1 Therapeutic Products Act (812.21)?	Is the device made of substances or combinations of substances that are systematically absorbed by the human body in order to achieve their intended purpose?	GMDN Code	EMDN code	BASIC UDI - DI	Risk class	Classific. Rule
1.	**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.	MedDO Legacy	No	No	No	58865	C0504	693882050000000000000302T	Class IIa	6
2.	**Angiographic Syringes**	Angiographic syringe is intended to deliver contrast media, which is compatible with high-pressure injection equipment during CT, DSA and MRI.	MedDO Legacy	No	No	No	15286	Z11039013	693882050000000000000012L	Class IIa	2
3.	**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.	MedDO Legacy	No	No	No	12155	Z12080299	693882050000000000000362A	Class IIa	7
4.	**Cervical Ripening Balloon**	The Cervical Ripening Balloon is a silicone double balloon catheter. Maximum balloon inflation is 80mL/balloon.	MedDO Legacy	No	No	No	47126	Z12080299	693882050000000000000372C	Class IIa	5

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (Annex VIII - REGULATION (EU) 2017/745)(Art.15 MedDO SR 812.213)

Date 1/17/2024

Stamp:

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