SCW MEDICATH LTD
No.4, Baolong 6th Road, Baolong Industrial Town,
Longgang District, Shenzhen 518116, P.R.China
Tel: 86 755 89312160 / 89312258
Fax: 86 755 89312239

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	SCW Medicath Ltd.
Manufacturer address and contact details	No.4, Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, 518116 Guangdong, P.R. China
Single Registration Number (SRN) (if available)	CN-MF-000019140

Authorised Representative name (if applicable)	Obelis s.a.
Authorised Representative address and contact details	Bd. Général Wahis 53; 1030 Brussels, BELGIUM
Single Registration Number (SRN) (if available)	BE-AR-000000106

Notified body name (if applicable)	TUV Rheinland LGA Products Gmbh □ See attached schedule
Notified body number (if applicable)	0197

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD 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 this Regulation requires the involvement of a notified body.

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	□ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	HD 601442320001 □See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024/5/26 □ See attached schedule
End date of extended validity/transition period	2028/12/31 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD 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 this Regulation requires the involvement of a notified body

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☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

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☑ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD 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 this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☑ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

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Signed for and on behalf of the manufacturer:

Full Company Name: SCW Medicath Ltd.

Location & Date: Shenzhen, 2024/4/7

Signature, Print Name, Title: Miriam Xie Miriam Xie, RA Manager

Contact Details (at least email): sales-5@scw-medicath.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Postpartum Balloon	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Cervical Ripening Balloon	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Guide Wire	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Hemostasis Valve Sets	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products	TUV Rheinland LGA Products	**2028/12/31**	**N/A**

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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			Gmbh 0197	Gmbh 0197		
Stopcock	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Balloon Inflation Device	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Connecting Tubing	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Manifold	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Pressure Bandage	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Colored piston specialty Syringe	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Dose-control Syringe	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products	TUV Rheinland LGA Products	**2028/12/31**	**N/A**

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			Gmbh 0197	Gmbh 0197		
Manifold Set	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Ureteral Stent Set	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Tracheostomy Tube Kits	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Percutaneous Nephrostomy Sets	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Locking Drainage Catheter	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
ERCP Guidewire	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Percutaneous Access Set	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products	TUV Rheinland LGA Products	**2028/12/31**	**N/A**

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			Gmbh 0197	Gmbh 0197		
Infusion Sets with needleless adapter	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Drainage Catheter Sets	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Introducer Needles	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Introducer Sets	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Transradial Introducer Sets	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Hemodialysis Catheterization Kit	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Angiographic Syringes	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products	TUV Rheinland LGA Products	**2028/12/31**	**N/A**

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			Gmbh 0197	Gmbh 0197		
Disposable Infusion Pumps	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Patient-Controlled Analgesic Infusion Pumps	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Disposable Pressure Transducers	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
I.V Cannulas	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**
Injection Cap	HD 601442320001	**2024/5/26**	TUV Rheinland LGA Products Gmbh 0197	TUV Rheinland LGA Products Gmbh 0197	**2028/12/31**	**N/A**