# TO WHOM SO EVER IT MAY CONCERN

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*
- 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 | **Poly Medicure Limited** |
| Manufacturer address and contact details. | Plot No. 104-105, Sector- 59, HSIIDC Industrial Area, Ballabhgarh, Faridabad, Haryana- 121004, India |
| Single Registration Number (SRN) | IN-MF-000003380 |

| | |
|---|---|
| Authorised Representative name | Obelis S.A |
| Authorised Representative address and contact details | B.D. General Wahis 53, 1030 Brussels, Belgium |
| Single Registration Number (SRN) | BE-AR-000000106 |

| | |
|---|---|
| Notified body name | ☒ See attached schedule |
| Notified body number | ☒ See attached schedule |
| Directive Certificate number(s) to which this confirmation is made | ☒ See attached schedule |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity | ☒ See attached schedule |
| End date of extended validity/transition period | ☒ 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*
- 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Certificate(s) covering the listed device(s) were issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.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

  ☐ 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.

  ☒ **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 have been made by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule and signed written agreement(s) is 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.

**Signed for and on behalf of the Manufacturer:**

Poly Medicure Limited, Faridabad

RD Sharma

General Manager- CQRA & PRRC

Date: 29 April 2024

E-mail: ramdas@polymedicure.com

**Schedule of Devices:**

The above Declaration is valid for the following devices:

| Identification of the device(s) (e.g., device name, family/group name device model or catalogue number) | Directive Certificate number(s) to which this confirmation is made | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity | Notified Body name and number that issued the Directive Certificate | Notified Body name and number where the MDR application was lodged/contract signed | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|---|---|---|---|---|---|---|
| IV Cannula / Catheter with/ without Safety feature | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Infusion Sets | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Burette Infusion sets | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Flow Regulators | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Extension line | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| CVP Manometers | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Stop cocks with/ without extension line | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Needle free connectors with/ without extension line | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Scalp Vein (Winged Infusion Set) with/without safety feature | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |

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|---|---|---|---|---|---|---|
| Manifolds with/without extension line | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Transfusion Pump Set | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Blood collection set with/without safety features | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Transfusion Sets (BT Set) | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Closed Wound Suction Unit | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Yankaur Suction Set (Suction tube and/or Handle) | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Thoracic Drainage Catheters with/without Trocar | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Redon Drainage Tubes | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Abdominal Drainage Set | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Under Water Sealed Drainage System | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |

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|---|---|---|---|---|---|---|
| Female catheters | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Nelaton catheters | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Foley Balloon Catheter | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Irrigation Set | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Nasogastric Feeding tubes with / without guidewires (Single & Dual port) / Levin's Tube | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Ryle's Tubes | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Feeding Bags | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Mucus Extractor with/ without bacterial Filter | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Suction Catheter | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Nasal Oxygen Catheter/ Cannula | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |

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|---|---|---|---|---|---|---|
| Oxygen Catheters | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Endotracheal Tube with Cuff / Without cuffed / Reinforced | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Catheter Mount | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Oxygen Mask | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Nebulizer Mask | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Venturi Mask | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Blood Line Set | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| AV Fistula Needle with/without safety features | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Peritoneal Dialysis Catheter Kit | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Luer caps | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |

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|---|---|---|---|---|---|---|
| Stomach Tubes | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Guedel Airways | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Peritoneal Dialysis Transfusion Set | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Umbilical Cord Clamp | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Urine Collection Bags with/without volume meter | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Trans Urethral Resection Set (TUR Set) | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Sterile Bottle caps | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Stylet (Obturators) | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Huber Infusion set with/without safety features | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Over The Needle (OTN) Catheter | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |

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|---|---|---|---|---|---|---|
| Arterial Cannula with / without Safety features | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Mini-midline catheter (Peripheral Catheter) | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Blood Collection Needle & Holder | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Vial Access Spike | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Rectal Catheter | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| HPVD Bottle with / without extension line and trocar | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Feeding tubes with/ without Guidewires | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Blood Bag (Transfer Bag) | G1 041938 0007 Rev. 00 | 26 May 2024 | TUV SUD Product service GmbH, NB# 0123 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Suction Control Valve | 13053-2018-CE-IND-NA-PS, Rev 1.0 | 26 May 2024 | DNV GL Presafe AS, NB# 2460 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |
| Breathing Circuit & Accessories | 13053-2018-CE-IND-NA-PS, Rev 1.0 | 26 May 2024 | DNV GL Presafe AS, NB# 2460 | TUV SUD Product service GmbH, NB# 0123 | 31.12.2028 | N/A |