Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 041938 0007 Rev. 00

Manufacturer:

POLY MEDICURE LIMITED
Plot No. 104-105, Sector-59
HSIIDC Industrial Area, Ballabhgarh
Faridabad, Haryana 121004
INDIA

Product Category(ies):

IV Cannula/ Catheter with / without Safety Features, Infusion Sets, Burette Infusion Sets, Flow Regulators, Extension Lines, Luer Caps, Stylet (Obturators), CVP Manometers, Stop cock with/without extension line, Needle free connectors with/without extension line, Scalp vein (Winged Infusion) Set (with / without safety features), Insulin Syringe, Huber Infusion set with / without safety features, Over the Needle (OTN) Catheter, Arterial Cannula with/without Safety Features, Manifolds with/without Extension line, Mini-midline Catheter (Peripheral catheter), Transfusion Pump Set, Luer Adaptors, Blood Bags, Blood Collection Set with / without Safety Features, Blood Collection Needle & Holder, Transfusion Sets (BT Sets), Closed Wound Suction Unit, Yankaur Suction Set (Suction tube and/or Handle), Thoracic Drainage Catheter (with/without Trocar), Redon Drainage Tube, Abdominal Drainage Set, Under Water Seal Drainage System, Female catheter, Nelaton catheter, Foley Balloon Catheter, Irrigation Set, Levins tube, Infant Feeding Tube, Ryle's Tube, Stomach Tube, Umbilical Catheter, Feeding Bag, Mucus Extractor with/without Bacterial Filter, Suction Catheter, Nasal Oxygen Catheter/ Cannula, Oxygen Catheter, Guedel Airways, Endotracheal Tubes (Plain, Cuffed, Reinforced), Catheter Mount, Oxygen Mask, Nebulizer Mask, Venturi Mask, Blood Line Set, Fistula Needle with / without Safety features, Peritoneal Dialysis Transfusion Set, Peritoneal Dialysis Catheter Kit, High Pressure Vacuum Drainage Bottle.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: IND2019081_CN

Valid from: 2020-06-17
Valid until: 2024-05-26

Date, 2020-06-17

Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Add value.
Inspire trust.

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POLY MEDICURE LIMITED
Sector-68, IMT
Plot No. 34
121004 FARIDABAD, HARYANA
INDIA

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TÜV SÜD Product Service GmbH
Confirmation Letter
CL 105485 0010 Rev. 00

Reference: TPS3025_G10

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 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following SRN Number:

SRN Number: IN-MF-000003380

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 TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer 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.

The transition timelines in accordance Article 120 (3) of MDR 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, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 105485 0010 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-03-13

TÜV SÜD Product Service GmbH Medical and Health Services	TÜV SÜD Product Service GmbH Medical and Health Services
Bardwala	Matthias
Project Handler (PH)	Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
Device 1 **IV Cannula / Catheter with/without Safety feature** **Basic UDI-DI: 890209510001CY**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 2 **Infusion Sets** **Basic UDI-DI: 890209514001DU**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 3 **Flow Regulators** **Basic UDI-DI: 890209513100DQ**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 4 **Stop cocks with/without extension line** **Basic UDI-DI: 890209513001DM**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 5 **Prefilled Syringe with 0.9% Saline Solution** **Basic UDI-DI: 890209590315GJ**	☒ Class IIb	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 6 **Arterial Cannula with/without Safety features** **Basic UDI-DI: 890209513426ER**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 7 **Manifolds with/without extension line** **Basic UDI-DI: 890209513710ER**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 8 **Mini-midline catheter (Peripheral Catheter)** **Basic UDI-DI: 890209513535EX**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 9 **Blood Collection Needle & Holder** **Basic UDI-DI: 890209588110H8**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 10 **Endotracheal Tube - plain/Cuffed/Reinforced**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Basic UDI-DI: 890209520150DV			
Device 11 **AV Fistula Needle with/without safety features** **Basic UDI-DI: 890209590030FX**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 12 **Dialyzer (Dialysis Filter)** **Basic UDI-DI: 890209590365GZ**	☒ Class IIb	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 13 **Disinfecting Port Protector** **Basic UDI-DI: 890209590309GP**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 14 **Vial Access Spike** **Basic UDI-DI: 890209513068EM**	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1S 105485 0008 Rev. 00; NB# 0123
Device 15 **Transfer Spike** **Basic UDI-DI: 890209590314GG**	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1S 105485 0008 Rev. 00; NB# 0123

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
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Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-03-13	TPS3025_G10	Initial issue