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www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 041938 0011 Rev. 00

Manufacturer:

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

SRN Manufacturer - IN-MF-000043009

Authorized Representative:

Obelis s.a.
Bd. Général Wahis 53, 1030 Brussels, BELGIUM

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 041938 0011 Rev. 00

Report No.: TPS3023
Valid from: 2025-02-24
Valid until: 2030-02-23

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-02-24

Digitally signed by Iarovoi Petru
Date: 2026.05.22 15:48:56 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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(Class IIa and Class IIb Devices)

No. G10 041938 0011 Rev. 00

Classification:	Class IIa
Device Group:	A01010201 - BUTTERFLY NEEDLES, WITH SAFETY SYSTEMS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A01010202 - BUTTERFLY NEEDLES, W/O SAFETY SYSTEMS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A01018099 - NEEDLES FOR INFUSION AND COLLECTION - OTHER ACCESSORIES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A010401 - ARTERIOVENOUS FISTULA NEEDLES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A03010101 - INFUSION CONTROLLERS WITH OR W/O AIR INLET
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A03010102 - INFUSION CONTROLLERS WITH FILTER (ALSO TRANSFUSION CONTROLLERS)
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A03010103 - INFUSION CONTROLLERS WITH FLOW REGULATOR
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A03010104 - INFUSION MICRO-CONTROLLERS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A030104 - FLOW REGULATORS
Intended Purpose:	-

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Classification:	Class IIa
Device Group:	A03020101 - LOW PRESSURE EXTENSION LINES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A03020102 - HIGH PRESSURE EXTENSION LINES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A03040299 - IRRIGATION KITS, SINGLE-USE - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0601010101 - DRAINAGE SYSTEMS WITH REDON TYPE RIGID CONTAINER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0601010102 - DRAINAGE SYSTEMS WITH RESERVOIR
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0601010103 - BELLOWS DRAINAGE SYSTEMS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0601010199 - DRAINAGE SYSTEMS WITH PREDEFINED SUCTION - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0601010401 - THORACIC DRAINAGES (STRAIGHT AND ANGLED)
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0601010499 - DRAINAGE PROBES - OTHER
Intended Purpose:	-

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Classification:	Class IIa
Device Group:	A060203 - PLEURAL DRAINAGES WITH VALVE AND KITS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0703 - STOPCOCKS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A07050202 - CAPS OR OBTURATORS, PERFORABLE WITHOUT NEEDLE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0799 - ADAPTERS, CONNECTORS, RAMPS, STOPCOCKS, CAPS - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A080101 - ENTERAL FEEDING BAGS AND CONTAINERS (INCLUDING THOSE VIA PUMP), SINGLE-USE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	C0101010101 - PERIPHERAL I.V. CATHETERS, W/O SAFETY SYSTEMS, WITH INJECTION VALVES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	C0101010102 - PERIPHERAL I.V. CATHETERS, W/O SAFETY SYSTEMS, W/O INJECTION VALVES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	C0101010201 - PERIPHERAL I.V. CATHETERS, WITH SAFETY SYSTEMS, WITH INJECTION VALVES
Intended Purpose:	-

Classification:	Class IIa

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Device Group:	C0101010202 - PERIPHERAL I.V. CATHETERS, WITH SAFETY SYSTEMS, W/O INJECTION VALVES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	C01010103 - PERIPHERAL I.V. CATHETERS, WITH INTEGRATED EXTENSIONS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	F020180 - ARTERIOVENOUS DIALYSIS LINES FOR HAEMODIALYSIS - HAEMOFILTRATION - HAEMODIAFILTRATION - ACCESSORIES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	F900101 - PERITONEAL DIALYSIS CATHETERS AND KITS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	G02020101 - NASOGASTRIC TUBES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	G020299 - GASTROINTESTINAL FEEDING/ASPIRATION TUBES - OTHER
Intended Purpose:	-
Classification:	Class IIa
Device Group:	G020301 - RECTAL TUBES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R01030101 - ENDOTRACHEAL TUBES, CUFFLESS, NOT REINFORCED
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R01030102 - ENDOTRACHEAL TUBES, CUFFLESS, REINFORCED
Intended Purpose:	-

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Classification:	Class IIa
Device Group:	R01030201 - ENDOTRACHEAL TUBES, CUFFED, NOT REINFORCED
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R01030202 - ENDOTRACHEAL TUBES, CUFFED, REINFORCED
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R02010101 - BREATHING CIRCUITS, W/O WATER TRAP
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R02010102 - BREATHING CIRCUITS, WITH WATER TRAP
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R020102 - COAXIAL BREATHING CIRCUITS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R020202 - MOBILE CATHETER MOUNTS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R020302 - RESPIRATORY CIRCUITS ADAPTERS AND CONNECTORS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R028099 - RESPIRATORY CIRCUITS AND MOUNT CATHETERS - ACCESSORIES NOT INCLUDED IN OTHER CLASSES
Intended Purpose:	-
Classification:	Class IIa

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Device Group: R03010201 - AIR/OXYGEN MASKS
Intended Purpose: -

Classification: Class IIa
Device Group: R03010202 - VENTURI MASKS
Intended Purpose: -

Classification: Class IIa
Device Group: R0301020301 - OXYGEN THERAPY STANDARD NASAL CANNULAS (GOGGLES)
Intended Purpose: -

Classification: Class IIa
Device Group: R03010204 - OXYGEN ADMINISTRATION TUBINGS
Intended Purpose: -

Classification: Class IIa
Device Group: R03010301 - AEROSOL THERAPY MASKS
Intended Purpose: -

Classification: Class IIa
Device Group: R040199 - VENTILATION FILTERS - OTHER
Intended Purpose: -

Classification: Class IIa
Device Group: R05010101 - RESPIRATORY SUCTION PROBES WITHOUT A CONTROL HOLE
Intended Purpose: -

Classification: Class IIa
Device Group: R05010102 - RESPIRATORY SUCTION PROBES WITH CONTROL HOLE
Intended Purpose: -

Classification: Class IIa
Device Group: R05010301 - SINGLE-CHAMBER MUCOUS MEMBRANE ASPIRATORS
Intended Purpose: -

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Classification:	Class IIa
Device Group:	U01010502 - NELATON CATHETERS, NON SELF-LUBRICATING
Intended Purpose:	-

Classification:	Class IIa
Device Group:	U020199 - URETERAL CATHETERS WITHOUT BALLOON - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	U020202 - URETERAL CATHETERS WITH FLUTE TIP WITH BALLOON
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z12019007 - IRRIGATORS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z1203020302 - NON–INVASIVE BLOOD PRESSURE MONITORING INSTRUMENTS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z121799 - BLOOD TRANSFUSION INSTRUMENTS - OTHER
Intended Purpose:	-

The validity of this certificate depends on conditions and/or is limited to the following: -

Revision History:

Rev.	Dated	Report	Description
00	2025-02-24	TPS3023	Initial issuance

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