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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 024169 0060 Rev. 01

Manufacturer:

EUROSETS S.R.L.
Strada Statale 12, 143
41036 Medolla (MO)
ITALY

SRN Manufacturer - IT-MF-000023171

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III (excluding custom-made implantable devices) or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

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:G15 024169 0060 Rev. 01

Report No.:	ITA200220020741
Preceding Certificate No.:	G10 024169 0051 Rev. 03 G15 024169 0060 Rev. 00
Valid from:	2026-07-10
Valid until:	2027-09-29
Date of Initial Issuance:	2026-03-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-07-10

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Certificate No. G15 024169 0060 Rev. 01

Classification:	Class III
Device Group:	MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools
Intended Purpose:	See product certificate
Classification:	Class IIb
Device Group:	C030101 - EXTRACORPOREAL CIRCULATION KITS
Intended Purpose:	The medical device in combination with perfusion Pump System, Tubing Set, Gas Blender and Heater-Cooler is intended to provide blood/ gas exchange and blood temperature regulation during cardiopulmonary bypass procedures. It is equipped with a hard-shell cardiotomy/venous reservoir device intended for use in extracorporeal perfusion, to collect, defoam and filter blood during cardiopulmonary bypass procedures. The device is furthermore intended to reduce the content of lipidic particles and leukocytes in the portion of extracavitary blood
Classification:	Class IIb
Device Group:	C030101 - EXTRACORPOREAL CIRCULATION KITS
Intended Purpose:	The medical device in combination with perfusion Pump System, Tubing Set and Oxygenator module is intended for use in extracorporeal perfusion, to collect, defoam and filter blood during cardiopulmonary bypass procedures. The medical device is furthermore intended to reduce the content of lipidic particles and leukocytes in the portion of extracavitary blood
Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	Monitoring equipment intended for the continuous and real time monitoring of patient physiologic parameters when undergoing to Extra Corporeal Circulation (ECC) support
Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	Detection equipment accessory intended to allow the continuous and real time monitoring of CO2 concentration parameter and Gas Flow parameter during Extra Corporeal Circulation (ECC)
Classification:	Class IIb
Device Group:	Z120502 - EXTRA-CORPOREAL CIRCULATION INSTRUMENTS
Intended Purpose:	Extra-corporeal perfusion pump system intended to pump blood in extra-corporeal circulation for pulmonary/cardiac/circulatory support
Classification:	Class IIb
Device Group:	Z120502 - EXTRA-CORPOREAL CIRCULATION INSTRUMENTS
Intended Purpose:	Heater-cooler device intended for cooling or heating water circulating through the heat exchanger during extra-corporeal circulation (ECC) procedures

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Certificate No. G15 024169 0060 Rev. 01

Classification:	Class IIa
Device Group:	MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
Classification:	Class IIa
Device Group:	MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools
The validity of this certificate depends on conditions and/or is limited to the following:	\

Revision History:

Rev.	Dated	Report	Description
00	2026-03-09	ITA200220015002	Supplemented: Device(s)/group of device(s) added
01	2026-07-10	ITA200220020741	Administrative merge / transfer to new Certificate Type

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