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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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 024169 0051 Rev. 03

Manufacturer:

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

SRN Manufacturer - IT-MF-000023171

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 024169 0051 Rev. 03

Report No.:	ITA2152879
Preceding Certificate No.:	G10 024169 0051 Rev. 02
Valid from:	2024-09-04
Valid until:	2027-09-29
Date of Initial Issuance:	2022-09-30

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-09-04

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Classification:	Class IIa
Device Group:	C0180 - ARTERO-VENOUS SYSTEM DEVICES - ACCESSORIES NOT INCLUDED IN OTHER CLASSES
Intended Purpose:	-

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 IIa
Device Group:	C03010301 - CARDIOPULMONARY SUPPORT KITS (C.P.S. AND ECMO)
Intended Purpose:	-

Classification:	Class IIa
Device Group:	C03010102 - OXYGENATOR KITS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	C03010399 - CIRCULATORY SUPPORT KITS - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	C030180 - EXTRACORPOREAL AND ASSISTED CIRCULATION DEVICES - ACCESSORIES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	C030199 - EXTRACORPOREAL AND ASSISTED CIRCULATION DEVICES - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z12050285 - EXTRA-CORPOREAL CIRCULATION INSTRUMENTS - CONSUMABLES
Intended Purpose:	-

Classification:	Class IIb
Device Group:	Z12030202 - MULTI–PARAMETER PATIENT MONITORS

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No. G10 024169 0051 Rev. 03

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:	Z1203020280 - MULTI-PARAMETER MONITORS - HARDWARE ACCESSORIES
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:	C03010199 - EXTRACORPOREAL CIRCULATION KITS - OTHER
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:	C03010102 - OXYGENATOR 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:	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.
The validity of this certificate depends on conditions and/or is limited to the following:	-
Revision History:	

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Rev.	Dated	Report	Description
00	2022-09-30	ITA1752429	-
01	2023-05-03	ITA1752429_2	Supplemented: Device(s)/group of device(s) added
02	2023-06-12	ITA1960359	Supplemented: Device(s)/group of device(s) added
03	2024-09-04	ITA2152879	Supplemented: Device(s)/group of device(s) added

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