



# Certificate

No. Q5 024169 0050 Rev. 04

**Holder of Certificate:** **EUROSETS S.R.L.**  
Strada Statale 12, 143  
41036 Medolla (MO)  
ITALY

**Certification Mark:**



**Scope of Certificate:** Design and development, Production and Distribution of Oxygenators, Heat Exchangers, Reservoirs, Circuits for Extracorporeal Circulation, Circuits for Transfusion, Autotransfusion, Blood Processing and Filtration, Washing Circuits, Filters, Orthopaedic and Cardiothoracic Drainages, Wound Therapy Disposables, Disposable Circuits for Partial Blood CO<sub>2</sub> Removal and Optional Hemofiltration in Extracorporeal Circulation, Disposable Centrifugal Pumps for the areas of Cardiac Surgery, Cardiovascular Surgery, Intensive Care Unit and Orthopaedic Surgery. Design and development, Production, Service and Distribution of Drainage Vacuum Generators, Wound Therapy Vacuum Generators, Blood Monitoring Systems for the Main Parameters of Extracorporeal Circulation, Equipment for Partial Blood CO<sub>2</sub> Removal and Optional Hemofiltration in Extracorporeal Circulation, Centrifugal Blood Pump Equipment, Heater-Cooler Units for Extracorporeal Circulation, for the areas of Cardiac Surgery, Cardiovascular Surgery, Intensive Care Unit and Orthopaedic Surgery. The provision of injection moulded plastic components for medical devices.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 024169 0050 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5_024169_0050_Rev.04)

**Report No.:** ITA200220003623

**Valid from:** 2024-09-26  
**Valid until:** 2025-08-24

**Date,** 2024-09-26



Christoph Dicks  
Head of Certification/Notified Body

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**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

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

See Scope of Certificate

**EUROSETS S.R.L.**  
Via Posta Vecchia 26, 41037 Mirandola (MO), ITALY

Production of Circuits for Extracorporeal Circulation, Circuits for  
Transfusion and Autotransfusion.

**EUROSETS S.R.L.**  
Via Campana 20, 41037 Mirandola (MO), ITALY

Warehousing

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