



Certificate

No. Q5 024169 0050 Rev. 03

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 CO₂ 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 CO₂ 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 and certification regulation of 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. 03

Report No.: ITA1846410

Valid from: 2022-08-25
Valid until: 2025-08-24

Date, 2022-08-24



Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q5 024169 0050 Rev. 03

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): EUROSETS S.r.l.
Strada Statale 12, 143, 41036 Medolla (MO), ITALY

See Scope of Certificate

/