



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 024169 0050 Rev. 05

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 Sterile and Non-Sterile Drainages and Fluid Collection Systems for Cardiac and Orthopaedic Surgery, Wound Therapy Devices, Intracavitary Suction Cannula, Accessories for Artero-Venous Devices, Blood-gas exchangers devices and accessories, Heat Exchangers, Reservoirs, Filters, Centrifugal Blood Pumps and Circuits for Extracorporeal Circulation and Transfusion, Blood recovery, Washing and Autotransfusion Devices, Accessories and Circuits, Blood-gas exchange circuits and hemofiltration circuits. Design and development, Production, Distribution and Servicing of Drainage Vacuum Generator, Wound Therapy Vacuum Generator, Autotransfusion Equipment, Monitoring Systems and Accessories for Extracorporeal Circulation, Blood-gas exchange and hemofiltration Equipment, Centrifugal Blood Pump Equipment, Heater-Cooler Units. The Provision of Injection Moulded Plastic Components for General Non-Active, Non-Implantable 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. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5_024169_0050_Rev_05)

Report No.: ITA200220005793

Valid from: 2025-08-25

Valid until: 2028-08-24

Date, 2025-06-04

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 Blood-gas exchangers devices and accessories,
Heat Exchangers, Reservoirs, Filters, Centrifugal Blood Pumps
and Circuits for Extracorporeal Circulation and Transfusion, Blood
recovery, Washing and Autotransfusion Devices, Accessories and
Circuits, Blood-gas exchange circuits and hemofiltration circuits.

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Quality Management and Regulatory Affairs.

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