



America

CERTIFICATE

No. QS6 024169 0049 Rev. 05

Certificate Holder:

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

Certification Mark:



Scope of Certificate:

See Page 2 for Overall Scope Statement.

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

**Australia TGA, Brazil ANVISA, Health Canada, Japan
MHLW / PMDA, USA FDA. See attached for listing of
specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 024169 0049 Rev. 05](http://www.tuvsud.com/ps-cert?q=cert:QS6_024169_0049_Rev.05)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:

F003193

Report No.:

ITA200220005793

Effective Date:

2025-05-28

Expiry Date:

2028-05-27

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Date of Issue: 2025-05-02

(Renee Walker)
Director, US Certification Body, MHS

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Overall Scope Statement:

Design and Development, Production and Distribution of Sterile and Non-Sterile Drainages and Fluid Collection Systems for Cardiac and Orthopaedic Surgery, 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 Monitoring Systems and Accessories for Extracorporeal Circulation, Centrifugal Blood Pump Equipment, Heater-Cooler Units

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Facility(ies):**EUROSETS S.R.L.**

Strada Statale 12, 143, 41036 Medolla (MO), ITALY

EUROSETS S.R.L.

Via Posta Vecchia 26, 41037 Mirandola (MO), ITALY

EUROSETS S.R.L.

Strada Statale 12, 139, 41036 Medolla (MO), ITALY

Facility Scopes:**EUROSETS S.R.L.**

Strada Statale 12, 143, 41036 Medolla (MO), ITALY

Design and Development, Production and Distribution of Sterile and Non-Sterile Drainages and Fluid Collection Systems for Cardiac and Orthopaedic Surgery, 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 Monitoring Systems and Accessories for Extracorporeal Circulation, Centrifugal Blood Pump Equipment, Heater-Cooler Units
REPs Facility ID: F003193

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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