



America

CERTIFICATE

No. QS6 024169 0049 Rev. 03

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, USA FDA, MHLW / PMDA. 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.03

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

REPs Facility ID: F003193
Report No.: ITA200220003623
Effective Date: 2024-09-29
Expiry Date: 2025-05-27

Page 1 of 3

Date of Issue: 2024-10-09

(Renee Walker)
Director, US Certification Body, MHS



America

CERTIFICATE

No. QS6 024169 0049 Rev. 03

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 Oxygenators, Heat Exchangers, Reservoirs, Circuits for Extracorporeal Circulation, Circuits for Transfusion, Autotransfusion, Blood Processing and Filtration, Washing Circuits, Filters, Orthopedic and Cardiothoracic Drainages, 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 Orthopedic Surgery

Design and Development, Production, Service and Distribution of Centrifugal Blood Pump Equipment for the areas of Cardiac Surgery, Cardiovascular Surgery, Intensive Care Unit

Page 2 of 3

Date of Issue: 2024-10-09

(Renee Walker)
 Director, US Certification Body, MHS

CERTIFICATE

No. QS6 024169 0049 Rev. 03

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.

Via Campana 20, 41037 Mirandola (MO), ITALY

Facility Scopes:

EUROSETS S.R.L.

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

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, 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 Centrifugal Blood Pump Equipment for the areas of Cardiac Surgery, Cardiovascular Surgery, Intensive Care Unit
REPs Facility ID: F003193

EUROSETS S.R.L.

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

Production of Circuits for Extracorporeal Circulation, Circuits for Transfusion and Autotransfusion
REPs Facility ID: F003193

EUROSETS S.R.L.

Via Campana 20, 41037 Mirandola (MO), ITALY

Warehousing
REPs Facility ID: F003193

Page 3 of 3

Date of Issue: 2024-10-09



(Renee Walker)
Director, US Certification Body, MHS