



America

CERTIFICATE

No. QS6 024169 0049 Rev. 02

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. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F003193**

Effective Date: **2022-06-16**

Expiry Date: **2025-05-27**

Page 1 of 3

Date of Issue: 2022-06-16

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services



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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. 16/2013
 - RDC ANVISA n. 23/2012
 - RDC ANVISA n. 67/2009

Canada

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

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
 - PMD Act

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, 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

Page 2 of 3

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

Facility Scopes: 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
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Page 3 of 3

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