



## **EC** Certificate

Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 024169 0048 Rev. 00

Manufacturer:

**EUROSETS S.r.I.** 

Strada Statale 12, 143 41036 Medolla (MO)

**ITALY** 

Facility(ies):

EUROSETS S.r.I.

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

Product Category(ies): Blood-gas exchanger for Extracorporeal partial CO2 removal in patients with hypercapnic respiratory failure and/or concurrent

acute renal failure.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf

Report No.:

ITA878315

Valid from:

2019-07-10

Valid until:

2024-05-26

Date.

2019-07-10

Stefan Preiß

1. Punil

Head of Certification/Notified Body