Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 024169 0047 Rev. 00

Manufacturer:

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

Facility(ies):

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

Product Category(ies):

Medical devices for transfusion (Micro-aggregates filters), Autotransfusion (Intra-operative and post-operative reservoir, Vacuum reducer, Anticoagulant and aspiration lines, Post-operative Autotransfusion systems), Drainage (Cardio-thoracic drainage systems, wound drainage systems with suction), Washing (Wound Washing, aspiration and cleaning systems, Pressure reducer), Vacuum Generators (for autotransfusion and post-operative drainage, wound drainage with suction), blood oxygenating devices for extracorporeal circulation (Oxygenators, venous reservoirs and Cardiotomy), Circuits and components for extracorporeal and infusional circulation (blood circuits with or without oxygenators, reservoirs, centrifugal blood pump, connector for transducer for flow monitoring system; cardioplegia and infusional circuits with or without heat exchanger; Connectors, Gas filters, Pre by-pass filters, cardioplegia and infusional solution filters, heat exchangers, Vascular tourniquet, one way valves; arterial filters). Autotransfusion system, blood processing (red blood cells concentration optical sensor, electromechanical clamp)

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

Report No.: ITA1281603

Valid from: 2019-07-13
Valid until: 2024-05-26

Date, 2019-07-03

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany