ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

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 0046 Rev. 02

Manufacturer:

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

Product Category(ies):

Blood oxygenating devices for extracorporeal circulation provided with cardiotomy reservoir for blood reduction of leucocytes and lipids and related circuits. Extracorporeal blood circuits with haemoconcentrators. Negative pressure wound therapy disposable devices. Negative pressure wound therapy vacuum generators. Blood monitoring unit for the main parameters of Extra Corporeal Circulation. Equipment and disposable circuits (e.g. tubing sets, blood gas exchanger, hemofilters, pressure transducers, syringes, bags and accessories) for partial blood CO_2 removal in extracorporeal circulation in patients with respiratory failure with optional circuit for hemofiltration treatment. Centrifugal blood pump equipment and disposable centrifugal blood pump. Heater-cooler unit for extracorporeal circulation. Extracorporeal life support and E.C.M.O. tubing sets, that may contain the components as listed in the attachment (see ATTACHMENT)

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 024169 0046 Rev. 02

Report No.: ITA1578139

Valid from: 2021-03-17
Valid until: 2024-05-26

Date, 2021-03-17

Christoph Dicks
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

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Supplement 001 2021-03-16 (ITA1578139)

Venous blood bags,
Graduated bags,
Cardiotomies,
Extracorporeal Membrane Oxygenator ECMO (adult, pediatric, new born) integrated of heat exchanger,
Centrifugal Pump,
DEHP Free Tubes,
Tygon Tubes,
DEHP Free Purge line tubings,
Straight connectors with or without luer lock connection,
Y-piece connectors with or without luer lock connection,
Luer and Luer Lock connectors with caps, Male and Female,
Stopcocks,
Adapters,
Protective caps,
Closure caps,
Pierceable stoppers,
Spikes,
Blood catchers,
Clamps,
Manometer protection device,
Temperature probes,
Gas filters,
Plastic cable ties

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