



Product Service

EC - CERTIFICATE

Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2 09 06 24169 017

Manufacturer: Eurosets s.r.l.
Via Statale 12, 143
41036 Medolla (MO)
ITALY

Facility(ies): Eurosets s.r.l.
Via 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)

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 products / product categories according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class IIb and III products an additional Annex III - certificate is mandatory. See also notes overleaf.

Report No.: ITA 194927

Valid until: 2014-09-01

Date, 2009-09-02

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

Page 1 of 1