ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 16 04 24169 033

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):

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

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.: ITA272689

Valid from: 2016-08-25
Valid until: 2019-07-12

Date, 2016-08-25

Stefan Preiß

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

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