DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 024169 0050 Rev. 00

Holder of Certificate: **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

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production and distribution of medical devices and components for transfusion, auto-transfusion, filtration, drainage, washing, vacuum generators, circuits and components for extracorporeal and infusional circulation, blood oxygenating devices for extracorporeal circulation, wound therapy, blood monitoring system for the main parameters of extracorporeal circulation, equipment and disposable circuit for partial blood CO_2 removal and optional hemofiltration in extracorporeal circulation. Moulding of plastic components for medical devices.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: ITA1251258

Valid from: 2019-08-27
Valid until: 2022-08-24

Date, 2019-08-27

Stefan Preiß
Head of Certification/Notified Body

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

A4 / 07.17

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