TÜV SÜD 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

TÜV SÜD 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 041502 0018 Rev. 01

Manufacturer:

F. M. S.p.A.
Via Farini 65 bis
13043 Cigliano (VC)
ITALY

Facility(ies):

FM Allbright S.R.L.
Str. Platforma n. 1, 547605 UNGHENI (MS), ROMANIA

FM Bizerte S.a.r.l.
Parc d'Activites Economiques BP37, 7017 Bizerte, TUNISIA

F. M. S.p.A.
Via Farini 65 bis, 13043 Cigliano (VC), ITALY

Product Category(ies):

Bloodlines and accessories for hemodialysis, hemodiafiltration and hemofiltration kit for preparation of blood components, pump infusion sets with/without needle, transfusion sets, scalp vein sets, needles for blood sampling

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.: ITA1345608

Valid from: 2019-10-16
Valid until: 2024-05-26

Date, 2019-10-16

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

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