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

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 I in sterile conditions, sterilised systems or procedure packs)

No. G2S 041502 0019 Rev. 01

Manufacturer

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

Facility(ies):

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

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

Product Category(ies):

Infusion sets for gravity

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. 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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