Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 038303 0025 Rev. 01

Manufacturer:

Pentaferte Italia S.r.l.
Viale Piane Nocella, 23
64012 Campli (TE)
ITALY

Facility(ies):

Pentaferte Italia S.r.l.
Viale Piane Nocella, 23, 64012 Campli (TE), ITALY

Pentaferte Italia S.r.l.
Via Modena 119, 44122 Ferrara, ITALY

Product Category(ies):

Syringes, infusion and transfusion sets, hypodermic needles, scalp-vein sets, sclerotherapy kit, enteral feeding tubes, extension tubes and accessories for enteral feeding, prefilled saline syringes for flushing

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.

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Valid until: 2022-06-01

Date, 2019-03-12

Stefan Preiß

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

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