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

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 17 04 38303 025

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

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.: ITA920766

Valid from: 2017-06-02
Valid until: 2022-06-01

Date, 2017-05-31

Stefan Preiß

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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

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 17 04 38303 026

Manufacturer:

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

Facility(ies):

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

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

Product Category(ies):

Syringes without needle, infusion sets without needle and accessories for enteral feeding

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.

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