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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 041808 0056 Rev. 04

Manufacturer:

**Shanghai Kindly Enterprise
Development Group Co., Ltd.**

No 658 Gaochao Road
201803 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Sterile 'Syringes, Scalp Vein Sets, Infusion Sets, Transfusion Sets, Hypodermic Needles, Infusion Sets with Burette, Urethral Catheter, Blood-collecting Needles, Dental Needles, Syringes for Insulin, Medical Tube (Feeding Tube), Medical Tube (Stomach Tube), Medical Tube (Suction Catheter), Medical Tube (Oxygen Cannula), Insulin Pen Needles, Seldinger Needle, Safe Syringe, Brachytherapy Seeding Needle, Extension sets, stopcocks, Injection kits' for Single Use, Sterile 'infusion Pump Administration Sets, Syringes with Shielded-Needle, Syringes with re-use prevention feature with needle, Zero residual small volume syringe, Irrigation needles' for single use.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

BJ19081705

Valid from:

2020-02-11

Valid until:

2024-05-26

Date,

2020-02-11

Christoph Dicks
Head of Certification/Notified Body

