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

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 081494 0016 Rev. 00

Manufacturer:

Sino Medical-Device Technology Co., Ltd.
6th Floor, Building 15
No. 1008, Songbai Road
Nanshan District
518055 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Sino Medical-Device Technology Co., Ltd (Guangming Branch)
Area C, 2nd Floor, Building 1, Han Haida Technology Innovation Park, Yulu Community, Guangming New District, 518132 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Sino Medical-Device Technology Co., Ltd.
6th Floor, Building 15, No. 1008, Songbai Road, Nanshan District, 518055 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

High-pressure Injector, Syringe Pump, Mammography
Infusion Pump, Enteral Nutrition Pump
Infusion Warmer, Infusion Monitoring System
Syringe Pump Station, Infusion Workstation
Enteral Feeding Sets for Single use
Single-use high-pressure angiographic syringes and accessories
Single-use high-pressure angiographic connecting tube
Single-use high-pressure angiographic transfer set

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.

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Date, 2019-01-02

Stefan Preiß

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