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 045885 0022 Rev. 02

Manufacturer:

Jiangsu Shenli Medical Production Co., Ltd.
No. 20, Changzheng Rd, Zhenglu
Tianning District
213111 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Sterile infusion sets with needles for single use,
Sterile transfusion sets with needles for single use,
Sterile syringes with needles for single use,
Sterile extension tubes for single use,
Sterile insulin syringes for single use,
Sterile scalp vein needles for single use,
Sterile hypodermic needles for single use,
Sterile three-way stopcocks for single use,
Sterile safety blood collection sets for single use

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G2 045885 0022 Rev. 02

Report No.: SH21156EXT01

Valid from: 2021-03-02
Valid until: 2024-05-26

Date, 2021-03-02

Christoph Dicks
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