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 045879 0021 Rev. 01

Manufacturer:

Jiangsu Kanghua Medical Equipment Co., Ltd.
Sanhekou
213115 Changzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Jiangsu Kanghua Medical Equipment Co., Ltd.
Sanhekou, 213115 Changzhou, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Disposable Syringes,
Disposable Infusion Sets,
Disposable Transfusion Sets,
Intravenous Needles for Single Use,
Burette-type Infusion Sets for Single Use,
Sterile Hypodermic Needles for Single Use,
Disposable Insulin Syringes,
Disposable Tuberculin Syringes,
Disposable Insulin Pen Needles

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.: SH19165EXT01

Valid from: 2019-09-30
Valid until: 2024-05-26

Date, 2019-09-30

Stefan Preiß
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