TÜV SÜD 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 068020 0011 Rev. 01

Manufacturer:

Sichuan Guangyuan Kangkang Medical Instrument Co., Ltd.
Qipanguan Industrial Park
Chaotian District
628013 Guangyuan City, Sichuan Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Infusion Sets for Single Use, Gravity Feed,
Single-use High-pressure Angiographic Syringes and Accessories,
Intravenous Needles for Single Use,
Connection Tube 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. See also notes overleaf.

Report No.: SH19386EXT01

Valid from: 2019-10-29
Valid until: 2024-05-26

Date, 2019-10-29

Christoph Dicks
Head of Certification/Notified Body

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

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD
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 068020 0011 Rev. 01

Facility(ies):

Sichuan Guangyuan Kangkang Medical Instrument Co., Ltd.
Qipanguan Industrial Park, Chaotian District,
628013 Guangyuan City, Sichuan Province,
PEOPLE'S REPUBLIC OF CHINA

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Sichuan Guangyuan Kangkang Medical Instrument Co., Ltd
四川省广元市康康医疗器械有限公司
Qipanguan Industrial Park, Chaotian district, Guangyuan City,
Sichuan Province, 628013, P.R.China
四川省广元市朝天区七盘关工业园区
Tel/电话:0839-8623616 Fax/传真:0839-8623615

KANGKANG Medical

EC DECLARATION OF CONFORMITY

Manufacturer: Sichuan Guangyuan Kangkang Medical Instrument Co., Ltd.
Address: Qipanguan Industrial Park, Chaotian District, 628013,
Guangyuan City, Sichuan Province, China

We declare under our sole responsibility that the medical device:

Single-use High-pressure Angiographic Syringes and Accessories
of class: IIa, rule 2
according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC Annex V and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: 93/42/EEC Annex V

Registration No.: G2 068020 0011
Valid until: 2024.05.26

Notified Body: TÜV SÜD Product Service GmbH (ID no. 0123) Ridlerstraße 65 80339 Munich

Place and date: Guangyuan 2024-01-02 General manager: