DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 068020 0012 Rev. 00

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

Certification Mark:

Scope of Certificate: **Production and Distribution of Sterile Hypodermic Syringes for Single Use, Infusion Sets for Single Use, Gravity Feed, Single-use High-pressure Angiographic Syringes and Accessories, Blood Transfusion Sets for Single Use, Sterile Hypodermic Needles for Single Use, Intravenous Needles for Single Use, Connection Tube for Single Use**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). 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:Q6 068020 0012 Rev. 00

Report No.: SH2038601

Valid from: 2021-07-15
Valid until: 2024-05-30

Date, 2021-07-15

Christoph Dicks
Head of Certification/Notified Body

CERTIFICAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Digitally signed by Iurcu Nicolae
Date: 2024.12.23 15:33:13 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

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No. Q6 068020 0012 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

See Scope of Certificate

.

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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 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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

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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 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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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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: Chen Xiao