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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 081681 0021 Rev. 00

Manufacturer:

Shanghai Kindly Medical Instruments Co., Ltd.
No.925 Jinyuan yi Road
201803 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Sterile Seldinger needle, Intervention accessories kit, Guidewire, Introducer tool kit, Introducer set, Bone cement syringe, Manifold kit, Stopcocks, Manifold, Infusion pumps, Pressure transducer for single use, Extension tube, Foley catheter, Safety syringe, Angiography Catheter, Y-connector Pack, Sterile Infusion connector and accessory for single use, Guiding Catheter, Micro Catheter.**

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.

Report No.: BJ19703071

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

Date, 2019-10-29

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Jighili Tatiana
Date: 2021.09.09 17:06:29 EEST
Reason: MoldSign Signature
Location: Moldova

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TÜV SÜD 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 081681 0021 Rev. 00

Facility(ies):

Shanghai Kindly Medical Instruments Co., Ltd.
No.925 Jinyuan yi Road, 201803 Shanghai, PEOPLE'S REPUBLIC OF CHINA

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

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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 081681 0017 Rev. 02

Manufacturer

Shanghai Kindly Medical Instruments Co., Ltd.
No.925 Jinyuan yi Road
201803 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Sterile 'Inflation device, Pressure bandage, Angiography syringe' for single use, Infusion sets without needle, syringes without needle, Burette infusion sets without needle, Vaginal Dilator.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: BJ19703071

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

Date, 2019-10-29

Christoph Dicks
Head of Certification/Notified Body

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TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 081681 0017 Rev. 02

Facility(ies):

Shanghai Kindly Medical Instruments Co., Ltd.
No.925 Jinyuan yi Road, 201803 Shanghai, PEOPLE'S REPUBLIC OF CHINA

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

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

Product Service

Certificate

No. Q5 081681 0020 Rev. 02

Holder of Certificate:
Shanghai Kindly Medical Instruments Co., Ltd.
No.925 Jinyuan yi Road
201803 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Shanghai Kindly Medical Instruments Co., Ltd.
No.925 Jinyuan yi Road, 201803 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate:
Design, Development, Production and Distribution of Sterile 'Inflation device, Pressure bandage, Angiography syringe, Infusion connector and accessory' for single use, Sterile Seldinger needle, Intervention accessories kit, Guidewire, Introducer tool kit, Introducer set, Bone cement syringe, Manifold kit, Stopcocks, Manifold for single use, Pressure transducer for single use, Infusion pumps for single use, Medical Wasting Containers, Infusion sets without needle, Syringes without needle, Burette infusion sets without needle, Extension tube, Y-connector Pack, Foley catheter, Vaginal Dilator, Safety syringe, Angiography Catheter, Guiding Catheter, Micro Catheter, Cardiovascular Guidewire, Cardiovascular Angiography Catheter.

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ1970302_BJ18703061_BJ18703063
Valid from: 2020-03-11
Valid until: 2021-12-06

Date, 2020-03-11

Christoph Dicks
Head of Certification/Notified Body

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