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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 050970 0014 Rev. 01

Manufacturer:

Jiangsu Kangbao Medical Equipment Co., Ltd.
78#, North Suzhong Road, Baoying
225800 Yangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Jiangsu Kangbao Medical Equipment Co., Ltd.
78#, North Suzhong Road, Baoying, 225800 Yangzhou,
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Infusion Set for Single Use, Scalp Vein Needle for SingleUse, Sterile Hypodermic Syringe for Single Use,Sterile Hypodermic Needle for Single Use, Burette-Type Infusion Sets for Single Use, Transfusion Sets for Single Use, Hemodialysis Care Kits, Disposable DEHP Free Infusion Set, Sterile Safety Scalp Vein Sets for Single Use, Sterile Safety Syringe for Single Use, Auto-disable Syringes for Single Use, Sterile Dissolve Needle, Sterile Safety Dissolve Needles for Single Use, Safety Hypodermic Needle for Single Use, Sterile Biopsy Needle for Single Use, Sterile Blood Lancet and Safety Blood Lancet for Single Use, Luer Cap, Surgical Kits, Insulin Syringe for Single Use, Blood Collection Needle for Single Use, Needle Free Connector, Heparin Cap, Single Use Connector(Three Way Stopcock, Intravenous Extension Tube, Connecting Tube), Scalp Vein Sets DEHP Free for Single Use, Disposable Infusion Set(PVC Free), Sterile Scalp Vein Sets for Single Use(PVC Free), Disposable IV Catheter

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.: SH19275EXT01

Valid from: 2019-10-08
Valid until: 2024-05-26
Date, 2019-10-08

Stefan Preiß
Head of Certification/Notified Body

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 050970 0015 Rev. 01

Manufacturer

Jiangsu Kangbao Medical Equipment Co., Ltd.
78#, North Suzhong Road, Baoying
225800 Yangzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):

Gauze Swab, Gauze Balls, Cotton Balls, Needle Counter, Safety Needle Counter, Disposable Dressing Kits,
Operation Room Turnover Kits, Sterile Oral/Enteral Syringe, Surgical Drapes, Sterile Oral/Enteral Cap, Sterile Bottle Adaptor

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.: SH1827516

Valid from: 2019-06-26
Valid until: 2023-05-27

Date, 2019-06-26

Stefan Preiß
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 050970 0015 Rev. 01

Facility(ies):

Jiangsu Kangbao Medical Equipment Co., Ltd.
78#, North Suzhong Road, Baoying, 225800 Yangzhou,
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. Q6 050970 0016 Rev. 01

Holder of Certificate: **Jiangsu Kangbao Medical Equipment Co., Ltd.**
78#, North Suzhong Road, Baoying
225800 Yangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate:

Production and Distribution of Disposable IV Catheter, Infusion Set for Single Use, Scalp Vein Needle for Single Use, Sterile Hypodermic Syringe for Single Use, Sterile Hypodermic Needle for Single Use, Sterile Vagina Dilator for Single Use, Lap Sponge, Gauze, Bandage, Medical Cotton Pad, Non-woven Cap/Face Mask/Coat/Shoes Covering, Cotton Ball, Cotton Applicator, Medical Absorbent Gauze, Cotton Wool, Drug Shaking Instrument, Thermometer-resetting Instrument and Medical Disposal Device, Burette-Type Infusion Sets for Single Use, Transfusion Sets for Single Use, Hemodialysis Care Kits, Sterile Vaginal Examination Aids, Flexible Needles, Disposable DEHP Free Infusion Set, Sterile Safety Scalp Vein Sets for Single Use, Sterile Safety Syringe for Single Use, Auto-disable Syringes for Single Use, Sterile Dissolve Needle, Sterile Safety Dissolve Needles for Single Use, Safety Hypodermic Needle for Single Use, Sterile Biopsy Needle for Single Use, Sterile Blood Lancet and Safety Blood Lancet for Single Use, Luer Cap, Surgical Kits, Gauze Swab, Gauze Balls, Needle Counter and Safety Needle Counter, Disposable Dressing Kits, Operation Room Turnover Kits, Sterile Oral/Enteral Syringe, Surgical Drapes, Insulin Syringe for Single Use, Alcohol Disinfection Pad, Blood Collection Needle for Single Use, Needle Free Connector, Heparin Cap, Single Use Connector(Three Way Stopcock, Intravenous Extension Tube, Connecting Tube), Scalp Vein Sets DEHP Free for Single Use, Disposable Infusion Set(PVC Free), Sterile Scalp Vein Sets for Single Use(PVC Free), Sterile Oral/Enteral Cap, Sterile Bottle Adaptor

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). See also notes overleaf.

Report No.: SH1927501

Valid from: 2020-02-01
Valid until: 2023-01-31

Date, 2020-01-15

Christoph Dicks
Head of Certification/Notified Body

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D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 050970 0016 Rev. 01

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):

Jiangsu Kangbao Medical Equipment Co., Ltd.
78#, North Suzhong Road, Baoying, 225800 Yangzhou,
PEOPLE'S REPUBLIC OF CHINA

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