



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 Infusion Set for Single Use, Scalp Vein Needle for SingleUse,

Category(ies):

Sterile Hypodermic Syringe for Single Use, Sterile
Hypodermic Needle for Single Use Burette-Type I

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

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Stefan Preiß
Head of Certification/Notified Body

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