



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 16 11 93445 006

Manufacturer:

Jiangsu KangJian

Medical Apparatus Co., Ltd.

No.16 Zhanqian Road

Jiangyan

225500 Taizhou

PEOPLE'S REPUBLIC OF CHINA



EC-Representative:

Linkfar Healthcare GmbH

St.-Franziskus-Str. 112 40470 Düsseldorf **GERMANY**

Product Category(ies): Vacuum Blood Collection System

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.:

SH1634310

Valid from:

2017-04-18

Valid until:

2021-04-10

2017-04-18 Date,

Stefan Preiß



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

Page 1 of 2



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 16 11 93445 006

Facility(ies):

Jiangsu KangJian Medical Apparatus Co., Ltd. No.16 Zhanqian Road, Jiangyan, 225500 Taizhou,

PEOPLE'S REPUBLIC OF CHINA

ш

7