



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 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

Date, 2017-04-18

Stefan Preiß



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

Page 1 of 2



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 16 11 93445 006****Facility(ies):****Jiangsu KangJian Medical Apparatus Co., Ltd.
No.16 Zhanqian Road, Jiangyan, 225500 Taizhou,
PEOPLE'S REPUBLIC OF CHINA**