ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 15 09 91609 002**

**Manufacturer:**

**Zhenjiang Kangli Medical Instrument Co., Ltd.**
Zhabei, Dalu Town, Zhenjiang New Area
212133 Zhenjiang, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:**

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

**Product Category(ies):**

**Disposable Sterilized Syringe with Needle,**
**Disposable Sterilized Needle,**
**Disposable Infusion Set with Needle,**
**Disposable Vacuum Blood Collection Needle**

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.:** SH1595601

**Valid from:** 2016-04-06
**Valid until:** 2021-04-05

04052768957948

**Date,** 2016-04-05

Stefan Preiß

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



TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 15 09 91609 002**

**Facility(ies):**

**Zhenjiang Kangli Medical Instrument Co., Ltd.**
**Zhabei, Dalu Town, Zhenjiang New Area, 212133**
**Zhenjiang, Jiangsu, PEOPLE'S REPUBLIC OF CHINA**



TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®