

## 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 08 74618 006

Manufacturer:

Jiangyin Jinfeng Medical Equipment Co., Ltd.

No. 74 Zhoujia Village, Jinfeng Village

Xuxiake Town 214407 Jiangyin

PEOPLE'S REPUBLIC OF CHINA



EC-Representative:

ZOUSTECH S.L.

Pso. Castellana, 141 - Planta 19

28046 Madrid

SPAIN

**Product** Category(ies): Sterile Hypodermic Syringes For Single Use(with Needles),

Infusion Sets For Single Use(with Needles), Sterile Hypodermic Needle For Single Use, Sterile Insulin Syringes For Single Use

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.:

SH1662201

Valid from:

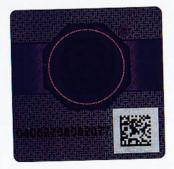
2017-02-07

Valid until:

2022-02-06

Date, 2017-02-07

Stefan Preiß



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

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No. G2 16 08 74618 006

Facility(ies):

Jiangyin Jinfeng Medical Equipment Co., Ltd. No. 74 Zhoujia Village, Jinfeng Village, Xuxiake Town, 214407 Jiangyin, PEOPLE'S REPUBLIC OF CHINA

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## CERTIFICATE

No. Q2N 16 08 74618 005

**Holder of Certificate:** Jiangyin Jinfeng Medical

Equipment Co., Ltd.

No. 74 Zhoujia Village, Jinfeng Village

Xuxiake Town 214407 Jiangvin

PEOPLE'S REPUBLIC OF CHINA



**Certification Mark:** 



Scope of Certificate: **Production and Distribution of** 

Sterile Hypodermic Syringes for Single Use(with Needles),

Infusion Sets for Single Use(with Needles), Sterile Hypodermic Needles for Single Use. Sterile Insulin Syringes for Single Use

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.:

SH1662201

Valid from:

2017-02-07

Valid until:

2020-02-06



Date, 2017-02-07

Stefan Preiß

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CERTIFICATE
No. Q2N 16 08 74618 005

Applied Standard(s): EN ISO 13485:2012 + AC:2012

Medical devices - Quality management systems -

Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009) DIN EN ISO 13485:2012

Facility(ies): Jiangyin Jinfeng Medical Equipment Co., Ltd.

No. 74 Zhoujia Village, Jinfeng Village, Xuxiake Town, 214407

Jiangyin, PEOPLE'S REPUBLIC OF CHINA

