ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ 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 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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Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

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

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

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

Product Service

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 Jiangyin
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

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

Product Service

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):

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

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