



CERTIFICATE

No. Q1N 18 04 03601 001

Holder of Certificate: Zhejiang MDKingdom Technology Co., Ltd.

> 508, 5th Floor, 28 Cang Ling Road Huzhen Town, Jinyun County

321404 Lishui City, Zhejiang Province PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Zhejiang MDKingdom Technology Co., Ltd.

> 508, 5th Floor, 28 Cang Ling Road, Huzhen Town, Jinyun County, 321404 Lishui City, Zhejiang Province, PEOPLE'S REPUBLIC OF

CHINA

Certification Mark:



Scope of Certificate: Design, Development, Production

Distribution and Service of Enteral Feeding

Pump, Infusion Pump, Syringe Pump.

Applied EN ISO 13485:2012 + AC:2012

Standard(s): Medical devices - Quality management systems -

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

DIN EN ISO 13485:2012

Upgrade required until 2019-03-31

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

BJ1722501 Report No.:

Valid from: 2018-07-12 Valid until: 2021-07-11

Date, 2018-07-12

Stefan Preiß

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EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 18 04 03601 002

Manufacturer: Zhejiang MDKingdom Technology Co., Ltd.

> 508, 5th Floor, 28 Cang Ling Road Huzhen Town, Jinyun County 321404 Lishui City, Zhejiang Province

PEOPLE'S REPUBLIC OF CHINA

EC-Representative: LAIPUDE GmbH

Schwarzenberger Str.46

47226 Duisburg **GERMANY**

Product Enteral Feeding Pump,

Infusion Pump, Syringe Pump. Category(ies):

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ1722501

Valid from: 2018-07-12 Valid until: 2023-07-11

Date, 2018-07-12 Stefan Preiß



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

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EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 18 04 03601 002

Facility(ies):

Zhejiang MDKingdom Technology Co., Ltd.

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