



Product Service

# CERTIFICATE

No. Q1N 16 06 52267 012

**Holder of Certificate:** **Zhejiang Fert Medical Device Co., Ltd.**

No.3618 HuanCheng South Road  
Wutong District  
314500 Tongxiang, Zhejiang  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Zhejiang Fert Medical Device Co., Ltd.  
No.3618 HuanCheng South Road, Wutong District, 314500 Tongxiang, Zhejiang, PEOPLE'S REPUBLIC OF CHINA



**Certification Mark:**



**Scope of Certificate:**

Design,Development,Production and Distribution of Single-use puncture set for local anaesthesia (Detailed as the attachment), Infusion sets with precision filters for single use, Single-use general anaesthesia kit (Detailed as the attachment), Disposable anaesthesia air filter, Single-use Respiration Loop (Detailed as the attachment), Disposable infusion pump, Pressure survey catheter, Vein Catheter prolonger, UV proof catheter prolonger, T connector for repeated injection, Catheter with 3-ways connector.

**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

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.

**Report No.:** BJ1680904

**Valid from:** 2016-08-16

**Valid until:** 2019-06-30

**Date,** 2016-08-16

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Attachment for Certificate no Q1N 16 06 52267 012  
Issue Dated: 2016-08-16

Supplement 001

For the product(s)/product category (ies):

**1. Single-use Puncture Set for Local Anaesthesia:**

Peripheral nerve block puncture needle, Epidural anaesthesia tube connector, Sterile hypodermic syringe, Glass syringe, Sterile hypodermic needle, Medical liquid filter for anaesthesia, Air filter for anaesthesia, Dressing towel, Operation towel, Latex surgical gloves, Gauze, Wound band, Disinfectant brush

**2. Single-use general anaesthesia kit:**

Tracheal tubes, Suction catheter for use in the respiratory tract, Gauze, Tooth cushion, Sterile hypodermic syringe, Latex surgical gloves, Guide wire, Airway protecting device, Laryngoscope, Education pipe

**3. Single-use respiration loop:**

Tubes, Anaesthesia face mask, Gas storage bursa

Munich, MHS-CRT

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