



Certificate

No. Q5 052267 0016 Rev. 02

Holder of Certificate: **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 Sales 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 heat and moisture exchange 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.

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.: BJ1980904

Valid from: 2019-07-01

Valid until: 2022-06-30

Date, 2019-06-11

Stefan Preiß
Head of Certification/Notified Body

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

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, Eduction pipe

3. Single-use respiration loop:

Tubes, Anaesthesia face mask, Gas storage bursa