



Product Service

# 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 16 06 52267 013

**Manufacturer:****Zhejiang Fert Medical  
Device Co., Ltd.**

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

**EC-Representative:****Shanghai International Holding  
Corp. GmbH (Europe)**

Eiffestraße 80  
20537 Hamburg  
GERMANY

**Product  
Category(ies):**

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),  
Single-use respiration loop (Detailed as  
the attachment), Pressure Survey catheter,  
Disposable anaesthesia air filter,  
Disposable infusion pump.

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.: BJ1680904

Valid from: 2016-08-16

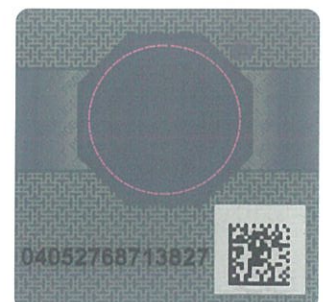
Valid until: 2019-10-20

Date, 2016-08-16

Stefan Preiß

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

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**No. G1 16 06 52267 013**

**Facility(ies):**

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Attachment for Certificate no G1 16 06 52267 013  
Issue Dated: 2016-08-16

Supplement 001

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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

Munich, MHS-CRT

Stefan Preiß

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