Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

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 052267 0013 Rev. 02

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

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 heat and moisture exchange 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.: BJ1980907

Digitally signed by Guțan Ghenadie
Date: 2021.09.14 20:08:40 EEST
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Location: Moldova

Valid from: 2019-08-23
Valid until: 2024-05-26

Date, 2019-08-23

Stefan Preiß
Head of Certification/Notified Body

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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
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Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 052267 0013 Rev. 02

Facility(ies):

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

attachment:

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.

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