





Certificate

No. Q5 082107 0010 Rev. 02

Holder of Certificate: Zhejiang Rungiang Medical

Instruments Co., Ltd

No. 618 Dade Road, Jiaxing Xiuzhou District

314031 Jiaxing City

PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design, Development, Production, Sales and Service of Sterile and Non-sterile Disposable Anaesthesia Needle and Anaesthesia Kit (see attachment), Sterile and Non-sterile Disposable Infusion Pump, Sterile and Non-sterile Disposable Heat and Moisture Exchange Filter, Sterile and Non-sterile Disposable Medical Filters (see attachment). Sterile and Nonsterile Disposable Breathing Tubes Intended for Use with Anaesthesia Apparatus and Ventilator (see attachment), Sterile and Non-sterile Disposable Urethral Catheterization Kit, Sterile and Non-sterile Disposable Sterile Urethral Catheter, Sterile and Non-sterile Disposable Spirometry Filter. Sterile and Non-sterile Needleless Airtight Infusion Connector Protector, Sterile and Non-sterile Disposable Connectors (drawing up straws, drawing up needles, syringe adaptors, caps, extension sets, stopcocks, stopcock with tube).

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.: BJ18794041

Valid from: 2019-06-11 Valid until: 2022-05-06

Date. 2019-06-11

Stefan Preiß

1. Punil

Head of Certification/Notified Body





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EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Zhejiang Rungiang Medical Instruments Co., Ltd. Facility(ies):

No. 618 Dade Road, Jiaxing Xiuzhou District, 314031 Jiaxing City,

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Attachment:

1. Anaesthesia Needle and Anaesthesia Kit include:

Epidural Needle, Spinal Needle, Epidural Catheter, Catheter Connector, Lor Syringe, Liquid Filter, Introducer Needle, Introducer Guide.

2. Disposable Medical Filters include:

Precision Liquid Filter, Transducer Protector, Medicine Liquid Filter for Anaesthesia.

3. Disposable Breathing Tubes Intended for Use with Anaesthesia Apparatus and Ventilator include:

Breathing Circuit Tube, Anaesthetic Masks, Rebreathing Bags.