ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 082107 0010 Rev. 03

Holder of Certificate: **Zhejiang Runqiang Medical Instruments Co., Ltd**
599 Ruifeng Street, Gaozhao District, Xiuzhou District
314031 Jiaxing City, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuvsud.com/ps-cert

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 Non-sterile 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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:Q5 082107 0010 Rev. 03

Report No.: BJ21079401

Valid from: 2022-05-07
Valid until: 2025-05-06

Date, 2022-05-05

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Iarovoi Petru
Date: 2022.09.08 12:18:23 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD
Product Service

Certificate

No. Q5 082107 0010 Rev. 03

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 Runqiang Medical Instruments Co., Ltd
599 Ruifeng Street, Gaozhao District, Xiuzhou District, 314031
Jiaxing City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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.

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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 17 12 82107 013

Manufacturer:

Zhejiang Runqiang Medical Instruments Co., Ltd
No. 618 Dade Road, Jiaxing Xiuzhou District
314031 Jiaxing City
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Disposable Anaesthesia Needle and Anaesthesia Kit

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.: BJ1779407

Valid from: 2018-05-07
Valid until: 2023-05-06

Date, 2018-03-29

Stefan Preiß

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

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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 17 12 82107 013

Facility(ies):

Zhejiang Runqiang Medical Instruments Co., Ltd
No. 618 Dade Road, Jiaxing Xiuzhou District, 314031 Jiaxing City,
PEOPLE'S REPUBLIC OF CHINA

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Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 17 04 82107 009

Manufacturer:

Zhejiang Runqiang Medical Instruments Co., Ltd
No. 618 Dade Road, Jiaxing Xiuzhou District
314031 Jiaxing City
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product:

Disposables for Anaesthesia and Respiration
Disposable Anaesthesia Needle and Anaesthesia Kit

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: BJ1679406

Valid from: 2018-03-01
Valid until: 2022-12-11

Date, 2018-03-01

Stefan Preiß

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

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Product Service

EC Certificate
EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 17 04 82107 009

Model(s): Disposable Anaesthesia Needle and Anaesthesia Kit

Parameters:

Epidural needle (AN-E),
diameters of 20~15G (0.9~1.8mm)
Effective lengths of 80 and 90mm.

Spinal needle (type I) AN-SI,
diameters of 27~15G (0.4~1.8mm)
Effective lengths of 38, 58, 75, 88, 100, 110 and 120mm.

Spinal needle (type I) AN-SI with introducer needle,
diameters of 27~15G (0.4~1.8mm)
Effective lengths of 38, 58, 75, 88, 100, 110 and 120mm.

Spinal needle (type II) AN-SII,
diameters of 27~20G (0.4~0.9mm)
Effective lengths of 75, 88, 100, 110 and 120mm.

Spinal needle (type II) AN-SII with introducer needle,
diameters of 27~20G (0.4~0.9mm)
Effective lengths of 75, 88, 100, 110 and 120mm.

The epidural anaesthesia kit (AS-E)
diameters of 15-18G (1.2-1.8mm)
consists of an epidural needle (with stylet made of
stainless steel or PP), an epidural catheter,
an introducer guide, a catheter connector,
a liquid filter (0.22um),
a lor (Loss of resistance) syringe (5mL, 7mL, 10mL).

The spinal anaesthesia kit (AS-S) with
or without introducer needle,
diameters of 20-25G (0.5-0.9mm)
consists of a spinal needle (type I),
a liquid filter (0.22um),
a lor (Loss of resistance) syringe (5mL, 7mL, 10mL).

The Combined spinal and epidural anaesthesia kit(AS-E/SII)
with or without introducer needle, consists of
an epidural needle (with stylet made of stainless steel
or PP), a spinal needle (type II),
an epidural catheter, a introducer guide,
a catheter connector, a liquid filter (0.22um),
a lor (Loss of resistance) syringe (5mL, 7mL, 10mL).

Thereinto, the epidural catheter
diameters: 0.8mm and 1.0mm
Effective length of 900mm – 1200mm.

Facility(ies): Zhejiang Runqiang Medical Instruments Co., Ltd
No. 618 Dade Road, Jiaxing Xiuzhou District, 314031 Jiaxing City,
PEOPLE'S REPUBLIC OF CHINA

Declaration of Conformity

Manufacturer:	Zhejiang Runqiang Medical Instruments Co. , Ltd. No. 599 Ruifeng Street, Gaozhao District, Xiuzhou District 314031 Jiaxing City, Zhejiang Proyince PEOPLE'S REPUBLIC OF CHINA TEL: +86-573-82287088, +86-573-82287018 FAX: +86-573-82287098
Medical Device:	Disposable Anaesthesia Needle And Anaesthesia Kit
Classification - Annex IX:	class III, Rule 7
Conformity assessment Route:	Annex II .3+ II.4

We, Zhejiang Runqiang Medical Instruments Co.,Ltd., herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices,
as amended by 2007/47/EEC;
All supporting documentation is retained at the premises of the manufacturer.
We, as the manufacturer, are exclusively responsible for the declaration of conformity.

Standards applied: **Related applicable harmonized STANDARDS (published in the official journal of the european communities)**

Notified Body:	TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany
identification number	CE 0123
(EC) Certificate(s):	G7 17 04 82107 009 G1 17 12 82107 013

EC REP

European Representative: Shanghai International Holding Corp. GmbH(Europe)
Eiffestrasse,80,20537,Hamburg,Germany Tel:0049-40-2513175, Fax :0049-40-255726

Start of CE-marking: Date of first CE marking (2012-12-12)

Place, Date of Declaration: JIAXIANG CITY, 2022-05-05

Signature:

Name: MR Fangming Xu
I behalf of Zhejiang runqiang medical Instruments Co,.Ltd
Position: Management representative