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

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 003771 0002 Rev. 00

Manufacturer

Zhejiang Quzhou Rongbo Medical Instrument Co., Ltd.
No.680, Century Road
Quzhou Economic Development Zone
324000 Quzhou City, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8,
80807 München, GERMANY

Product Category(ies):

Sterile Syringe for Single Use without Needle,
Sterile Infusion Set for Single Use without Needle,
Sterile Precision Filter Infusion Set for Single Use without Needle

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH18131301

Digitally signed by Iarovoi Petru
Date: 2021.12.30 21:08:33 EET
Reason: MoldSign Signature
Location: Moldova

Valid from: 2018-11-13
Valid until: 2023-11-12

Date, 2018-11-13

Stefan Preiß

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L. REPUBLICA MOLDOVA Sogno S.R.L. IDNO 1004600013854

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

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

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ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 003771 0002 Rev. 00

Facility(ies):

**Zhejiang Quzhou Rongbo Medical Instrument Co., Ltd.
No.680, Century Road, Quzhou Economic Development Zone, 324000 Quzhou City, Zhejiang Province,
PEOPLE'S REPUBLIC OF CHINA**

-/-

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L. • REPUBLICA MOLDOVA • IDNO 1004600013854 • MUN. SINAU

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

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

Product Service

Certificate

No. Q6 003771 0001 Rev. 00

Holder of Certificate:

Zhejiang Quzhou Rongbo Medical Instrument Co., Ltd.
No.680, Century Road
Quzhou Economic Development Zone
324000 Quzhou City, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

**Zhejiang Quzhou Rongbo Medical Instrument Co., Ltd.
No.680, Century Road, Quzhou Economic Development Zone,
324000 Quzhou City, Zhejiang Province, PEOPLE'S
REPUBLIC OF CHINA**

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate:

Production and Distribution of Sterile Syringe for Single Use with/without Needle, Sterile Infusion Set for Single Use with/without needles, Sterile Precision Filter Infusion Set for Single Use with/without Needle

Applied Standard(s):

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH18131301

Valid from: 2018-11-13
Valid until: 2021-11-12

Date, 2018-11-13

Stefan Preiß

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

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 17 09 99455 002

Manufacturer:
Jiangsu Kezhi Medical Technology Co.,Ltd
Laozhangji Industrial Park
Huaiyin District
223300 Huaian
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):
Disposable Nasal Oxygen Cannula,
Disposable Suction Connecting Tube,
Disposable Oxygen Mask,
Disposable Infusion Device with Needle

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH17120101

Valid from: 2018-02-09
Valid until: 2023-02-08

04052767965449

Date, 2018-02-09

Stefan Preiß

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

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Product Service

EC Certificate
Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 17 09 99455 002

Facility(ies):

Jiangsu Kezhi Medical Technology Co.,Ltd
Laozhangji Industrial Park, Huaiyin District, 223300
Huaian, PEOPLE'S REPUBLIC OF CHINA

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