

No. Q6 003771 0001 Rev. 00

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

Certification Mark:



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

Date. 2018-11-13



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

Valid from: 2018-11-13

Valid until: 2023-11-12

Date, 2018-11-13

I. Pennip

Stefan Preiß



TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD

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



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

-/-



Page 2 of 2

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

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

TUV®