



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 18 03 42464 031

Manufacturer:

**Zhejiang Gongdong Medical
Technology Co., Ltd.**

No.10 Beiyuan Ave., Huangyan
318020 Taizhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:**

**Shanghai International Holding
Corp. GmbH (Europe)**

Eiffestraße 80
20537 Hamburg
GERMANY

**Product
Category(ies):**

**Disposable Vacuum Blood Collection System,
Disposable Umbilical Cord Scissors**

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.:

SH18111EXT01

Valid from:

2018-06-09

Valid until:

2023-06-08



Date, 2018-04-05

S. Preiß

Stefan Preiß

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

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(Devices in Class IIa, IIb or III)

No. G2 18 03 42464 031**Facility(ies):**

Zhejiang Gongdong Medical Technology Co., Ltd.
No.10 Beiyuan Ave., Huangyan, 318020 Taizhou,
Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Zhejiang Gongdong Medical Technology Co., Ltd.
No.39 Beiyuan Ave., Huangyan, 318020 Taizhou,
Zhejiang, PEOPLE'S REPUBLIC OF CHINA





Product Service

Certificate

No. Q5 042464 0033 Rev. 00

Holder of Certificate: Zhejiang Gongdong Medical Technology Co., Ltd.

No.10 Beiyuan Ave., Huangyan
318020 Taizhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Plastic Centrifuge Tubes, Plastic Pipette Tips, Plastic Culture Dishes, Plastic Forceps, Plastic Test Tubes, Plastic Sample Cups, Plastic First Aid Cases and Disposable Vacuum Blood Tubes, Disposable Vacuum Blood Collection Systems, Disposable Vaginal Speculum, Disposable Sterile Swabs, Transportation Swabs with Medium, Micro Blood Collection Tubes, Capillary Blood Collection Tubes, Vacuum Urine Collection Sets, Disposable Umbilical Cord Scissors Disposable Specimen Container, Needle Holder, Disposable Non Vacuum Blood tubes, Disposable Anoscope, Disposable Loop Stick, Sterile Vaginal Applicator, Unicirc (Universal Circumcision Device), Sampling Scoops, Plastic Transfer Pipette, Plastic Storage Bottles, Disposable Otoscope Tips (Ear Specula)

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.: Sh1811120

Valid from: 2019-03-04

Valid until: 2022-02-28

Date, 2019-03-04

Stefan Pfeiffer





Certificate

No. Q5 042464 0033 Rev. 00

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 Gongdong Medical Technology Co., Ltd.
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