

CE Technical File

Declaration of Conformity

Manufacturer: Zhejiang Gongdong Medical Technology Co.,Ltd.
Beicheng Industrial Area 318020 Huangyan China

European

Representative: Shanghai International Holding corp.GmbH(Europe)
Eiffestrabe 80 20537 Hamburg GERMANY

Product Name: Centifugation tube&rack

Model Number: 0.2-50ml&rack

EMDN Code: W05019099

Classification (IVDD): Other

Conformity Assessment Route: IVDD Annex III

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied:

ISO14971:2019

ISO13485:2016

ISO20417:2021

ISO11135-1:2021

ISO 11607-1/2:2017

Notified Body: TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65 • 80339 München Germany

Identification number: Not applicable

(EC) Certificate(s): Not applicable

Expire date of the Certificate: Not applicable

Start of CE Marking: Not yet

Place, Date of Issue: HuangYan 2021-09-06

Signature:

中卫峰

Name: Zhong Weifeng

Position: General Manager





Certificate

No. Q5 042464 0033 Rev. 05

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
Non-active Medical Devices
(See following Pages)**

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 042464 0033 Rev. 05

Report No.: SH2211103

Valid from: 2023-07-24
Valid until: 2025-02-28

Date: 2023-07-24

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 042464 0033 Rev. 05

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

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, Disposable Vaginal Speculum, Disposable Sterile Swabs, Transportation Swabs with Medium, Disposable Umbilical Cord Scissors, Disposable Specimen Container, Needle Holder, 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), Medical Isolation Face Shield, Medical Isolation Goggles, Urine Sediment Counting Board, Oral Drug Delivery Device, Mucus trap, Embedding Cassette, Culture Plate, Ear Curette, Cell Culture Flask, Sterile Erlenmeyer Flasks, Plastic Funnel, Urine Transfer Straw, Urine Collection Kit

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

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, Disposable Vacuum Blood Tubes, Disposable Vacuum Blood Collection Systems, Micro Blood Collection Tubes, Capillary Blood Collection Tubes, Vacuum Urine Collection Sets, Needle Holder, Disposable Non Vacuum Blood tubes, Disposable Anoscope, Disposable Loop Stick, Sampling Scoops, Plastic Transfer Pipette, Plastic Storage Bottles, Disposable Otoscope Tips (Ear Specula), Disposable Aqueous Humor Collector, Saliva Collection Kit, Medical Isolation Face Shield, Medical Isolation Goggles, Urine Sediment Counting Board, Virus Collection and Preservation System, Oral Drug Delivery Device, Mucus trap, Embedding Cassette, Culture Plate, Ear Curette, Cell Culture Flask, Cell Factory, Serological Pipettes, PRF Tubes, Plastic Funnel, Urine Transfer Straw, Urine Collection Kit

Zhejiang Gongdong Medical Technology Co., Ltd.
No. 88 Jingxian Road, Huangyan, 318020 Taizhou, Zhejiang,
PEOPLE'S REPUBLIC OF CHINA

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

Certificate

No. Q5 042464 0033 Rev. 05

First Aid Cases, 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), Disposable Aqueous Humor Collector, Saliva Collection Kit, Medical Isolation Face Shield, Medical Isolation Goggles, Urine Sediment Counting Board, Virus Collection and Preservation System, Oral Drug Delivery Device, Mucus Trap, Embedding Cassette, Culture Plate, Ear Curette, Cell Culture Flask, Cell Factory, Serological Pipettes, PRF Tubes, Plastic Funnel, Urine Transfer Straw, Urine Collection Kit

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書證言訖

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