







Certificate

No. Q5 042464 0033 Rev. 07

Holder of Certificate: Zhejiang Gongdong Medical

Technology Co., Ltd.No.10 Beiyuan Ave., Huangyan 318020 Taizhou, Zhejiang

318020 Taizhou, Zhejiang PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development Production and Distribution of

Non-active Medical Devices and IVD Consumables for Sample Collection and Transportation (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, Certification, Validation and Verification Regulations 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.07

Report No.: SH24011102

 Valid from:
 2025-03-01

 Valid until:
 2028-02-28

Date, 2025-02-11 Christoph Dicks

Head of Certification/Notified Body







Certificate

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Applied Standard(s): ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

Facility(ies): Zhejiang Gongdong Medical Technology Co., Ltd.

No.10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang,

PEOPLE'S REPUBLIC OF CHINA

Non-active Medical Devices:

Design and Development, Production and Distribution of Plastic Pipette Tips, Plastic Forceps, Plastic First Aid Cases, Disposable Vaginal Speculum, Disposable Sterile Swabs For Sample Collection, Transportation Swabs with Medium, Disposable Umbilical Cord Scissors, Needle Holder, Disposable Anoscope, Disposable Loop Stick, Sterile Vaginal Applicator, Unicirc(Universal Circumcision Device), Sampling Scoops, Disposable Otoscope Tips(Ear Specula), Medical Isolation Face Shield, Medical Isolation Goggles, Oral Drug Delivery Devices, Mucus Trap, Ear Curette, Plastic Funnel, Urine Collection Kit. IVD Consumables for Sample Collection and Transportation: Design and Development, Production and Distribution of Plastic Centrifuge Tubes, Plastic Culture Dishes, Plastic Test Tubes, Plastic Sample Cups, Disposable Specimen Container, Plastic Storage Bottles, Culture Plate, Urine Sediment Counting Board, Embedding Cassette, Plastic Transfer Pipette, Cell Culture Flask, Sterile Erlenmeyer Flasks, Urine Transfer Straw.

Zhejiang Gongdong Medical Technology Co., Ltd.

No.39 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Non-active Medical Devices:

Design and Development, Production and Distribution of Plastic Pipette Tips, Plastic Forceps, Plastic First Aid Cases, Needle Holder, Disposable Anoscope, Disposable Loop Stick, Sampling Scoops, Disposable Otoscope Tips (Ear Specula), Saliva Collection Kit, Medical Isolation Face Shield, Medical Isolation Goggles, Mucus Trap, Ear Curette, Plastic Funnel, Suction Canister Kit.

IVD Consumables for Sample Collection and Transportation: Design and Development, Production and Distribution of Plastic Centrifuge Tubes, Plastic Culture Dishes, Plastic Test Tubes, Plastic Sample Cups, Plastic Storage Bottles, Culture Plate, Urine Sediment Counting Board, Embedding Cassette, Plastic Transfer Pipette, Cell Culture Flask, Cell Factory, Serological Pipettes.

Zhejiang Gongdong Medical Technology Co., Ltd.

No. 88 Jingxian Road, Huangyan, 318020 Taizhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Non-active Medical Devices:









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Design and Development, Production and Distribution of Plastic Pipette Tips, Plastic Forceps, Plastic First Aid Cases, Disposable Vaginal Speculum, Disposable Sterile Swabs For Sample Collection, Transportation Swabs with Medium, Vacuum Urine Collection Sets, Disposable Umbilical Cord Scissors, Needle Holder, Disposable Anoscope, Disposable Loop Stick, Sterile Vaginal Applicator, Unicirc (Universal Circumcision Device), Sampling Scoops, Disposable Otoscope Tips (Ear Specula), Disposable Aqueous Humor Collector, Saliva Collection Kit, Medical Isolation Face Shield, Medical Isolation Goggles, Virus Collection and Preservation System, Oral Drug Delivery Device, Mucus Trap, Ear Curette, PRF Tubes, Plastic Funnel, Urine Collection Kit, Specimen Bag, Mouth Piece for Endoscopes, Disposable Vaginometer.

IVD Consumables for Sample Collection and Transportation:
Design and Development, Production and Distribution of Plastic
Centrifuge Tubes, Plastic Culture Dishes, Plastic Sample Cups,
Plastic Test Tubes, Plastic Transfer Pipette, Disposable Vacuum
Blood Tubes, Micro Blood Collection Tubes, Capillary Blood
Collection Tubes, Disposable Specimen Container, Disposable
Non Vacuum Blood Tubes, Plastic Storage Bottles, Culture Plate,
Urine Sediment Counting Board, Serological Pipettes, Embedding
Cassette, Cell Culture Flask, Cell Factory, Urine Transfer Straw,
Disposable Urine Collection Tube.

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