



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

BS-IVDR-099



Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class A Devices in Sterile Condition)

No. V11 042464 0039 Rev. 00

Manufacturer:

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

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

SRN Manufacturer:

CN-MF-000005694

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).

The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The involvement of the notified body is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V11_042464_0039_Rev.00

Report No.:

SH2211102

Valid from:

2023-04-11

Valid until:

2028-04-10

Issue date: 2023-04-11

Marta Carnielli
Head of Notified Body IVD





Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zfg.de
BS-IVDR-099



Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class A Devices in Sterile Condition)

No. V11 042464 0039 Rev. 00

Classification: Class A
Device Group: W050101 - BLOOD COLLECTION DEVICES
Intended Purpose: IVR 0803 - Specimen receptacles referred to in point 2.5 (rule 5),
under c), of Annex VIII to Regulation (EU) 2017/746

The validity of this certificate
depends on conditions and/or
is limited to the following:

Revision History:

Rev.	Dated	Report	Description
00	2023-04-11	SH2211102	Initial issuance





DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 042464 0033 Rev. 07

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 and IVD Consumables for Sample Collection and Transportation (See following Pages)**

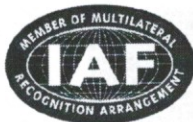
The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification 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





Product Service

Certificate

No. Q5 042464 0033 Rev. 07

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:





Product Service

Certificate

No. Q5 042464 0033 Rev. 07

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.

J.

