

CE Technical File

Declaration of Conformity

Manufacturer: Zhejiang Gongdong Medical Technology Co.,Ltd.
No.10 Beiyuan Ave., Huangyan 318020 Taizhou , Zhejiang China

European

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

Product Name: Tube

EMDN Code: W050301020102

Classification (IVDD): Other

Conformity Assessment Route: IVDD

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:

ISO13485:2016, ISO11135:2014, ISO14971:2019, ISO 15223-1:2021,EN ISO 11607-1:2019, EN ISO 20417:2021

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 2022.01.10

Signature: 

Name: HuiYong Sheng 浙江拱东医疗器械股份有限公司

Position: General Manager 浙江拱东医疗器械股份有限公司





Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitschutz
bei Arzneimitteln und
Medizinprodukten
www.zfa.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





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 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zfz.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 |





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

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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