Digitally signed by Iurchevici Valeriu
Date: 2026.04.28 15:41:36 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

AUTHORIZATION LETTER

To whom it may concern

MANUFACTURER

Zhejiang Gongdong Medical Technology Co., Ltd

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

Do hereby authorize

"Echipamed Plus" SRL

str. Valea Trandafirilor, 24B, of.2-7, MD-2001, Chisinau, Republic of Moldova

As our distributor and representative in Republic of Moldova for the medical disposable plastic ware products produced by Zhejiang Gongdong Medical Technology Co., Ltd.

This authorization letter valid from March 7, 2025 to March 6, 2028.

Zhejiang Gongdong Medical Technology Co., Ltd

March 7, 2025

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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BS-IVDR-099

TÜV SÜD 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

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Zhejiang Gongdong Medical Technology Co.,Ltd.
Beicheng Industrial Area 318020 Huangyan China
http://www.chinagongdong.com

GONG拱东DONG

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)
Eiffestrabe 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 Shi
Position： General Manager

浙江拱东医疗器械股份有限公司 GONGDONG MEDICAL TECHNOLOGY CO.,LTD.

Zhejiang Gongdong Medical Technology Co.,Ltd.
No.10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang,
People's Republic of China.
http://www.chinagongdong.com

GONG拱东DONG

Declaration of Conformity

Manufacturer: Zhejiang Gongdong Medical Technology Co.,Ltd.
No.10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China

European Representative: ZOUSTECHSL.
Pso.Castellana,141-Planta 19,28046-Madrid,Spain

Product Name: Specimen container
Model/Type: with spoon: 20ml,30ml,40ml,60ml,90ml,100ml,120ml;
without spoon: 20ml,30ml,40ml,60ml,80ml,90ml,100ml,120ml;

UMDNS Code: 14303
Classification (IVDD): Others
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. Zhejiang Gongdong Medical Technology Co.,Ltd. is exclusively responsible for the DoC.

DIRECTIVES

General applicable directives:

General applicable directive:
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.

StandardApplied:
ISO14971:2019 ISO13485:2016
ISO11135-1:2014 ISO 15223-1:2021

Place, Date of Issue: HuangYan 2021-03-13

Signature:
Name: WeiFeng Zhong
Position: General Manager

ZHEJIANG GONGDONG MEDICAL TECHNOLOGY CO.,LTD 浙江 拱东医疗器械股份有限公司

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD 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:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

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

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD 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:

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

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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