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

Product Service

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

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

Marta Carnielli
Head of Notified Body IVD

Issue date: 2023-04-11

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

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

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

REPUBLICA MOLDOVA mun. CHIȘINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ECHIPAMED-PLUS" IDNO 1003600077677

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

TÜV®

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.
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.
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：
Name： Zhong Weifeng
Position： General Manager

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

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： Pipette tip
Model/Type： with filter:10ul,20ul 30ul,50ul,100ul,200ul,300ul,1000ul,1250ul;
without filter: 10ul,20ul,30ul,50ul,100ul,200ul,300ul,1000ul 1250ul

UMDNS Code： 16883
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.

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

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

TÜV SÜD
Product Service

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:

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

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany
TÜV®

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

Product Service

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

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

TÜV SÜD
Product Service

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

./.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®