



Zhejiang Gongdong Medical Technology Co., Ltd

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

TEL: 0086-576-84082905 FAX: 0086-576-84050789

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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

Valea Trandafirilor 24B, of.80, 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 18th, May, 2018 to 17th, May, 2021



Zhejiang Gongdong Medical Technology Co., Ltd

Date 2018-05-18

Jim Qiu

Sales Manage





Product Service

Certificate

No. Q5 042464 0033 Rev. 00

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 Plastic Centrifuge Tubes, Plastic Pipette Tips, Plastic Culture Dishes, Plastic Forceps, Plastic Test Tubes, Plastic Sample Cups, Plastic First Aid Cases and 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)

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). See also notes overleaf.

Report No.: Sh1811120

Valid from: 2019-03-04

Valid until: 2022-02-28

Date, 2019-03-04

Stefan Pfeiffer





Certificate

No. Q5 042464 0033 Rev. 00

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

Zhejiang Gongdong Medical Technology Co., Ltd.
No.39 Beiyuan Ave., Huangyan, 318020 Taizhou,
Zhejiang, PEOPLE'S REPUBLIC OF CHINA



CE Technical File

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

Product Name: Centrifugation tube, Cryotube

Model Number: 0.2-50ml & rack

EDMA Code: 1404010100

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:

ISO14971:2007	ISO13485: 2003	EN980: 2008
ISO11135-1:2007	ISO 11607-1/2:2006	EN1041:2008;
ISO11737-1:2006		

Notified Body: TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65 • 80339 München Germany

Identification number: Not applicable

(EC) Certificate(s): Not applicable

Place, Date of Issue: HuangYan 2019-02-16

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

Signature: _____

Name: HuiYong Shi

Position: General Manager



旋慧勇