Zhejiang Gongdong Medical Technology Co., Ltd
ADD: No.10,Beiyuan Ave.,Huangyan, Taizhou,Zhejiang,China,318020
TEL: 0086-576-84082905 FAX: 0086-576-84050789
URL: http://www.chinagongdong.com E-mail: Jim@chinagongdong.com

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

Digitally signed by Iurchevici Valeriu
Date: 2021.02.17 18:46:04 EET
Reason: MoldSign Signature
Location: Moldova

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

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 18 03 42464 031

Manufacturer:

Zhejiang Gongdong Medical Technology Co., Ltd.
No.10 Beiyuan Ave., Huangyan
318020 Taizhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

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

Product Category(ies):

Disposable Vacuum Blood Collection System,
Disposable Umbilical Cord Scissors

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH18111EXT01

Valid from: 2018-06-09
Valid until: 2023-06-08

0405276852621

Date, 2018-04-05

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

Product Service

EC Certificate
Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 18 03 42464 031

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

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

TÜV SÜD
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:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

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 Preiß

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D-ZM-11321-01-00

TÜV SÜD
Product Service

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

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