



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



Zhejiang Gongdong Medical Technology Co.,Ltd

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

<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
European
Representative: Shanghai International Holding corp.GmbH(Europe)
Eiffestrabe 80 20537 Hamburg GERMANY
Product Name: Test tube & tube stopper & rack
Model Number: 2ml to 16ml
EDMA Code: 1190019000
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

EN1041:2008;

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

Place, Date of Issue: HuangYan 2019-02-10

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

施慧勇

Rev. A



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