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., Economic Development Zone,Huangyan,
Taizhou,Zhejiang,China,318020

European Representative: Shanghai International Holding corp.GmbH(Europe)
Eiffestrabe 80 20537 Hamburg GERMANY

Product Name: Micro blood collection tubes

Model: No Additive (plain) and with additive

UMDNS Code: 16384

Classification (IVDD, Aneex III): others

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. Zhejiang Gongdong Medical Technology Co.,Ltd. is exclusively responsible for the DoC.

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:

ENISO13485:2016;	EN ISO 15223-1-2016;	ENISO11607-1:2019
ENISO14971:2019;	ISO11135-1：2014;	EN 1041:2008+A1:2013;

(EC) Certificate(s): Not applicable

Start of CE Marking: Not yet

Place, Date of Issue: HuangYan 2020-12-16

Signature: _____

Name: WeiFeng Zheng

Position: General Manager

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

Digitally signed by Iliev Ana
Date: 2023.08.23 18:07:06 EEST
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Location: Moldova