

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: Disposable Vacuum Blood Tube
Model: No Additive (plain) and with additive
EDMA Code: 1303909000
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.

All applicable harmonized Standards

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, 2018-12

Signature: 
ZHEJIANG GONGDONG

Name: Wei Feng Zhong
MEDICAL TECHNOLOGY CO.,LTD.

Position: General Manager
