

## CE Technical File

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### *Declaration of Conformity*

Manufacturer: Zhejiang Gongdong Medical Technology Co.,Ltd.  
Beicheng Industrial Area 318020 Huangyan China

European

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

Product Name: Centifugation tube&rack

Model Number: 0.2-50ml&rack

EMDN Code: W05019099

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:

ISO14971:2019

ISO13485:2016

ISO20417:2021

ISO11135-1:2021

ISO 11607-1/2:2017

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 2021-09-06

Signature: \_\_\_\_\_

Name: Zhong Weifeng

Position: General Manager











