



# Zhejiang SKG Medical Technology Co., Ltd

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## *CE Declaration of Conformity*

Manufacturer: Zhejiang SKG Medical Technology Co.,Ltd.

NO.39 Anye Road, Gaoqiao Street, Huangyan 318020 Taizhou, Zhejiang

PEOPPLE'S REPUBLIC OF CHINA

European

Representative: Shanghai International Holding corp.GmbH(Europe)

Eiffestrabe 80 20537 Hamburg GERMANY

Product Name: Sample Cup

Model Number: BS-200, 700

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:

ISO13485:2003, ISO11135-1:2007, ISO14971:2007, ISO 15223-1-2012

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 2021-12-17

Signature:

Name: Sujian

Position: General Manager

