



Zhejiang SKG Medical Technology Co., Ltd

Add: No.39, Anye Road, Gaoqiao Street, Huangyan, Taizhou, Zhejiang, China, 318020

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Declaration of Conformity

Manufacturer: Zhejiang SKG Medical Technology Co., Ltd
No.39, Anye Road, Gaoqiao Street, Huangyan, Taizhou,
Zhejiang, China, 318020

European

Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80 20537 Hamburg GERMANY

Product Name: Micro Centrifugation Tube 1.5mL

Maximum force: 24000xG

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: 2016 EN980: 2008
ISO11135-1:2007 ISO 11607-1/2:2006 EN1041:2008;
ISO11737-1:2006

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 2022-03-03

Signature:

Name: Sujian

Position: General Manager

