



Zhejiang SKG Medical Technology Co., Ltd

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

Tel: 0086-576-84031666 Fax: 0086-576-84036668 Http://www.skgmed.com

CE Declaration of Conformity

Manufacturer: Zhejiang SKG Medical Technology Co., Ltd.

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

PEOPLE'S REPUBLIC OF CHINA

European

Representative: Shanghai International Holding corp.GmbH(Europe)

Eiffestrase 80 20537 Hamburg GERMANY

Product Name: Specimen Container

Model Number: 4ml-150ml

EDMA Code: 1401079000

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 2021-12-15

Signature: 

Name: Sujian

Position: General Manager



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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Product Service

Certificate

No. Q5 042464 0463 Rev. 03

Holder of Certificate:

**Zhejiang Skg Medical
Technology Co.,Ltd**

No.39 Anye Road.,Gaoqiao Steet
Huangyan 318020 Taizhou,Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of
Plastic Centrifuge Tubes, Plastic Pipette Tips, Plastic
Culture Dishes, Plastic Forceps, Plastic Test Tubes,
Plastic Sample Cups, Plastic First Aid Cases and
Disposable Vacuum Blood Tubes, Disposable Vacuum
Blood Collection Systems, Disposable Vaginal Speculum,
Disposable Sterile Swabs, Transportation Swabs with
Medium, Micro Blood Collection Tubes, Capillary Blood
Collection Tubes, Vacuum Urine Collection Sets,
Disposable Umbilical Cord Scissors Disposable
Specimen Container, Needle Holder, Disposable Non
Vacuum Blood tubes, Disposable Anoscope, Disposable
Loop Stick, Sterile Vaginal Applicator, Unicirc (Universal
Circumcision Device), Sampling Scoops, Plastic Transfer
Pipette, Plastic Storage Bottles

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above
has established and is maintaining a quality management system, which meets the requirements of the
listed standard(s). See also notes overleaf.

Report No.:

SH1911101

Valid from:

2022-01-27

Valid until:

2024-02-28



C.D.M.

Date,

2022-01-27

Christoph Dicks

Head of Certification/Notified Body