



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](http://www.skgmed.com)

To whom it may concern

Manufacturer's Authorization

Date: 15th Nov 2023

We Zhejiang Skg Medical Technology Co., Ltd, who are official manufacturers of disposables medical and laboratory consumables, having factories at No.39, Anye Road, Gaoqiao Street, Huangyan, Taizhou, Zhejiang, China, 318020, do hereby declare that

“ECHIPAMED-PLUS” SRL
str. Valea Trandafirilor 24 “B”, of. 2-7
MD-2001, Chisinau
Republic of Moldova

is our official distributor and local representative for disposables medical and laboratory consumables of Zhejiang Skg Medical Technology Co., Ltd, in the territory of the Republic of Moldova.

We declare that above mentioned company is authorized to do registration, quote and sell disposables medical and laboratory consumables, manufactured by us.

We hereby extend our full warranty with respect to the Goods offered by the above company.

This authorization letter will remain valid until 31.12.2024.

Zhejiang Skg Medical Technology Co., Ltd



Jim Qiu
Director



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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT


DAkkS
 Deutsche
 Akkreditierungsstelle
 D-ZM-11321-01-00



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:



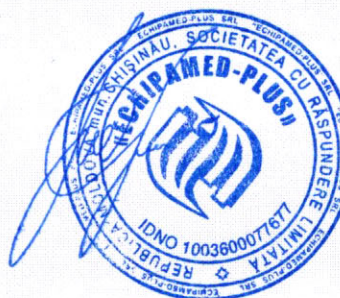
Scope of Certificate:

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. Dicks

Date, 2022-01-27

Christoph Dicks
 Head of Certification/Notified Body





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

PEOPLE'S REPUBLIC OF CHINA

European

Representative: Shanghai International Holding corp.GmbH(Europe)

Eiffestrasse 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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Declaration of Conformity

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Zhejiang, China, 318020

European

Representative: SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Product Name: Centrifugation Tube
Model Number: 1-50ml
EDMA Code: 1404010100
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


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 2023-02-03

Signature: 
Name: Sujian
Position: General Manager





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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)
Eiffestrabe 80 20537 Hamburg GERMANY

Product Name: Disposable Vacuum Blood Collection Tube

Brand Name: SKGVACU

EDMA Code: 1303909000

Classification (IVDD, Annex III) – General IVD Device

Conformity Assessment Route – IVDD 98/79 EC Directive, self-declaration

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; EN980:2003; EN14820:2004;
ISO14971:2007; ISO11137-1: 2006 EN1041:2008; EN-552:1994;

Place, Date of Issue: HuangYan 2021-12-17

Signature:

Name: Sujian
Position: General Manager





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European

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

Product Name: Pipette and tips

Model Number: 0.2-50ml

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 2021-12-15

Signature: 

Name: Sujian

Position: General Manager





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PEOPLE'S REPUBLIC OF CHINA

European

Representative: Shanghai International Holding corp. GmbH(Europe)

Eiffestrasse 80 20537 Hamburg GERMANY

Product Name: Sample Cup

Model Number: BS-200, 700

Classification (IVDD): Other

Conformity Assessment Route: IVDD Annex III

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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

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Identification number: Not applicable

(EC) Certificate(s): Not applicable

Expire date of the Certificate: Not applicable

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Place, Date of Issue: HuangYan 2021-12-17

Signature: 

Name: Sujian

Position: General Manager

