

## 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

To whom it may concern

#### Manufacturer's Authorization

Date: 17th Dec.2021

We Zhejiang Skg Medical Technology Co,,Ltd, who are official manufacturers of medical disposable plastic ware products, having factories at No.39 Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang CHINA, 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 medical disposable plastic ware products of Zhejiang Skg Medical Technology Co.,Ltd in the territory of the Republic of Moldova.

We declare that above mentioned company is authorized to quote, sell, subsequently negotiate

and sign contracts, as well as to perform installation and after sales service of medical disposable plastic ware products 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 31.12.2022.

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浙江双康医疗科技有限公司 ZHEJIANG SKG MEDICAL TECHNOLOGY CO.,LTD.

Jim Qiu Director

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

PEOLPLE'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 Manag

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**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

Christoph Dicks

Date,

2022-01-27

Head of Certification/Notified Body