Digitally signed by Iurchevici Valeriu
Date: 2023.11.15 11:35:44 EET
Reason: MoldSign Signature
Location: Moldova

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: 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

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

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
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 Manager

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

Rev. B

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

TÜV SÜD
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:

TÜV SÜD
tuv-sud.com/ps-cert

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

"TECHPAMED-PLUS" SOCIETATEA CU RASPUNDERE LIMITATA IDNO 1003600077677 REPUBLICA MOLDOVA mun. CHISINAU

Date, 2022-01-27

Christoph Dicks
Head of Certification/Notified Body

TÜV®

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany