



# 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: 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

