

# Medizinischer Gesichtsschutz

#bleib geschützt

#bleib gesund



3-lagig  
Gültiges CE Zertifikat  
ISO-13485:2016  
EN 14683:2019  
BFE >98%  
IIR Fluid Resistant  
Einheitsgröße  
ab April 2020 verfügbar



Export Carton



Polybag



Inner box



## Declaration of Conformity

**Manufacturer**

Name: JIANGSU KANGBAO MEDICAL EQUIPMENT CO.,LTD  
Address: No.78, North Suzhong Road Baoying 225800  
Yangzhou PEOPLE'S REPUBLIC OF CHINA

**European Representative :**

Name: **Shanghai International Holding Corp. GmbH(Europe)**

Address: Eiffestrasse 80, 20537 Hamburg Germany

**Product Name: Medical face masks**

**Models:** KB/I, KB/II, KB/IIR; **Specification:** Size L, Size M, Size S.

**Classification:** I (Non-sterilized )

We herewith declare that the above mentioned product meet the provisions of the following EC Council Directive and Standards (MDD/93/42/EEC). The products meet prospective uses and all supporting documentation are retained under the premise of manufacturer. we are exclusively responsible for this Doc.

### Directives

**General Applicable Directive:** MDD 93/42/EEC

**Standards Applied :** EN14683:2019, ISO10993, ISO22609,  
EN ISO11737

**Place, Date:** Jiangsu .Baoying

Name: Liu Hui

Signature: *Liu Hui*

Position: General Manager

Date: 2020-03-06

**CE**

EC Declaration of Conformity

KB/CE-011-03

TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ CERTIFICAT



## Certificate

No. Q6 050970 0016 Rev. 01

**Holder of Certificate:** **Jiangsu Kangbao Medical Equipment Co., Ltd.**  
 78#, North Suzhong Road, Baoying  
 225800 Yangzhou  
 PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:**

Production and Distribution of Disposable IV Catheter, Infusion Set for Single Use, Scalp Vein Needle for Single Use, Sterile Hypodermic Syringe for Single Use, Sterile Hypodermic Needle for Single Use, Sterile Vagina Dilator for Single Use, Lap Sponge, Gauze, Bandage, Medical Cotton Pad, Non-woven Cap/Face Mask/Coat/Shoes Covering, Cotton Ball, Cotton Applicator, Medical Absorbent Gauze, Cotton Wool, Drug Shaking Instrument, Thermometer-resetting Instrument and Medical Disposal Device, Burette-Type Infusion Sets for Single Use, Transfusion Sets for Single Use, Hemodialysis Care Kits, Sterile Vaginal Examination Aids, Flexible Needles, Disposable DEHP Free Infusion Set, Sterile Safety Scalp Vein Sets for Single Use, Sterile Safety Syringe for Single Use, Auto-disable Syringes for Single Use, Sterile Dissolve Needle, Sterile Safety Dissolve Needles for Single Use, Safety Hypodermic Needle for Single Use, Sterile Biopsy Needle for Single Use, Sterile Blood Lancet and Safety Blood Lancet for Single Use, Luer Cap, Surgical Kits, Gauze Swab, Gauze Balls, Needle Counter and Safety Needle Counter, Disposable Dressing Kits, Operation Room Turnover Kits, Sterile Oral/Enteral Syringe, Surgical Drapes, Insulin Syringes for Single Use, Alcohol Disinfection Pad, Blood Collection Needle for Single Use, Needle Free Connector, Heparin Cap, Single Use Connector(Three Way Stopcock, Intravenous Extension Tube, Connecting Tube), Scalp Vein Sets DEHP Free for Single Use, Disposable Infusion Set(PVC Free), Sterile Scalp Vein Sets for Single Use(PVC Free), Sterile Oral/Enteral Cap, Sterile Bottle Adaptor


The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH1927501  
**Valid from:** 2020-02-01  
**Valid until:** 2023-01-31


**Date,** 2020-01-15  
  
 Christoph Dicks  
 Head of Certification/Notified Body



AA / 07.17  
 TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT



**Certificate**  
No. Q6 050970 0016 Rev. 01



Product Service

**Applied Standard(s):** EN ISO 13485:2016  
 Medical devices - Quality management systems -  
 Requirements for regulatory purposes  
 (ISO 13485:2016)  
 DIN EN ISO 13485:2016

**Facility(ies):** Jiangsu Kangbao Medical Equipment Co., Ltd.  
 78#, North Suzhong Road, Baoying, 225800 Yangzhou,  
 PEOPLE'S REPUBLIC OF CHINA

Page 2 of 2  
 TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

