

	泰州市新康医用器材有限公司 Taizhou Xinkang Medical Materials Co., Ltd.	文件编号 Doc No.: XINKANG-TF-MTM	版本号 Edition: B0	页码 Page: 5
	口对口呼吸器-技术文件 Mouth to Mouth Mask- CE Technical File	符合性声明 EC Declaration of Conformity	生效日期 Effective Date: 2021-05-18	

## XINKANG-TF-SGS-02 符合性声明

### EC Declaration of Conformity

**Manufacturer:**

Name: Taizhou Xinkang Medical Materials Co., Ltd.  
 Add: No.18, Wuzhou(South) Road, 225300 Taizhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA  
 Tel: +86(0523) 86848901 Fax: +86(0523) 86848738

**European Representative:**

Name: Shanghai International Holding Corp. GmbH(Europe)  
 Address: Eiffestrasse 80, 20537 Hamburg, Germany

**Product Name:** Mouth to Mouth Mask

**Model/Size:** 3155, 3156, 3157, 3158, 3165, 3166, 3167, 3168

**Intended use:** Mouth to Mouth Mask is mainly used for artificial respiration to protect rescuers from cross-infection. It is a barrier between rescuers and patients.

**Product Picture:**



**Risk Class of the Device:** I, rule I according to ANNEX VIII Chapter III of Medical Device REGULATION (EU) 2017/745.

**The EMDN code:** R030199 SRN:CN-MF-000012941

**Product Certification Conformity Assessment Route:** Annex II, Annex III of EU 2017/745

**Basic UDI-DI:**

Model	UDI	Model	UDI
3155	6953102631556	3165	6953102631655
3156	6953102631563	3166	6953102631662
3157	6953102631570	3167	6953102631679
3158	6953102631587	3168	6953102631686

We herewith declare that the above-mentioned products meet the provisions of the following Medical Device REGULATION (EU) 2017/745. All technical documentations are retained under the promises of the manufacturer.

**Taizhou Xinkang Medical Materials Co., Ltd.** is exclusively responsible for the declaration of conformity.

**General applicable directives:**

Medical Device REGULATION (EU) 2017/745

**Standards applied:**

List of (harmonized) standards (see part 07 of this technical file) for which documented evidence of compliance can be provided.

Notified Body according to CE/ISO Certificate **TÜV SÜD Product Service GmbH**

Zertifizierstelle: Ridlerstraße, 65, 80339 München, Germany

Identification Number: 0123

CE/ISO Certificate No.: **Q6 056732 0021 Rev. 02** Valid until: **2024-03-04**

Position: General Manager

Name: Tang Yujun

Date: **2021-03-22**

Place: Taizhou

Signature of issue person:

