

## Declaration of Conformity

### MANUFACTURER

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### AUTHORIZED REPRESENTATIVE:

Name: Shanghai International Holding Corp. GmbH (Europe)  
Add: Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: +49-40-2513175 Fax: +49-40-255726 E-mail: [shholding@hotmail.com](mailto:shholding@hotmail.com)

### MEDICAL DEVICE:

Model Name: Non-invasive Positive Pressure Ventilation Mask

TYPE: Full Mask : Large (L), Medium (M), Small (S);  
Nasal Mask : Large (L), Medium (M), Small (S)

UMDNS CODE: 15230

**Classification:** IIa (Rule two, Annex IX, MDD 93/42/EEC)

**Conformity Assessment Procedure:** Annex II

### **DIRECTIVES**

We declare that the Non-invasive Positive Pressure Ventilation Mask is conform to the following Medical Device Directive:

COUNCIL DIRECTIVE 93/42/EEC as amended by 2007/47/EC concerning medical devices.

Standard Applied: All applicable Harmonized EN Standards.

Notified Body: SGS Belgium NV

Address: SGS House Noorderlaan 87 2030 Antwerp Belgium

Identification Number: CE 1639

(EC) Certificate(s): CN19/41067

Expire date of the Certificate: 2024-03-08

Date CE mark was affixed: 2019-12-16

Place, Date of Issue: 2019-12-16/ Ningbo

SIGNATURE :



NAME: LINNA LUO/ Manager, QA Dept.

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*Better breathing, Better life.*