

Manufacturer :

Name : Xiamen Winner medical Co., Ltd.

Address : 4F, No. 98 Huli Industrial Park, Mei Xi Dao, TongAn, Xiamen, China

Zip code : 361100 Tel. : +86-592-7238368

Fax : +86-592-7238287



Declaration of Conformity

Manufacturer:

Name: Xiamen Winner Medical Co., Ltd.

Address: 4F, No. 98 Huli Industrial Park, Mei Xi Dao, TongAn, 361100
Xiamen, PEOPLE'S REPUBLIC OF CHINA

European

Representative:

Name: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product Name

1. **Silicone/SEBS/PVC Manual Resuscitators
(Masks, Positive End Expiratory Pressure Valve, Oxygen
Tube, Reservoir)**
2. **Resuscitation Mask**
3. **Nebulizer**
4. **Oxygen Mask**
5. **Continuous Positive Airway Pressure Mask/Non-Invasive
Ventilation mask**

Classification (MDD, Annex IX): **IIa, rule 2**Conformity Assessment Route: **Annex V.3**

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. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Notified Body:

TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339,
München, Germany

Identification number:

CE0123

(EC) Certificate(s):

G20784760007 Rev.00

Expire date of the Certificate:

2024-05-26

Place, Date of Issue:

Xiamen, 2020-06-09

Signature:

Name:

Mr. Qing Wu

Position:

Vice General Manager