



Product Service

# EC Certificate

## Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

No. G2 16 09 78476 005

**Manufacturer:****Xiamen Winner Medical Co., Ltd.**

4F, No.98 Huli Industrial Park

Mei Xi Dao

TongAn

361100 Xiamen

PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:****Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80

20537 Hamburg

GERMANY

**Product Category(ies):**

Silicone/SEBS/PVC Manual Resuscitators  
(Masks, Positive End Expiratory Pressure Valve,  
Oxygen Tube, Reservoir), Resuscitation Mask,  
Continuous Positive Airway Pressure  
Mask/Non-Invasive Ventilation Mask,  
Nebulizer, Oxygen Mask

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

**Report No.:**

SH16717EXT01

**Valid from:**

2016-12-13

**Valid until:**

2021-12-12

**Date,** 2016-10-17

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2





Product Service

**EC Certificate****Production Quality Assurance System**

Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

**No. G2 16 09 78476 005****Facility(ies):**

Xiamen Winner Medical Co., Ltd.  
4F, No.98 Huli Industrial Park, Mei Xi Dao, TongAn,  
361100 Xiamen, PEOPLE'S REPUBLIC OF CHINA

