



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



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 078476 0007 Rev. 00**

**Manufacturer:**

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

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

**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.:**

SH19717EXT01

**Valid from:**

2020-02-20

**Valid until:**

2024-05-26

**Date,**

2020-02-20

Christoph Dicks  
Head of Certification/Notified Body





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Xiamen, PEOPLE'S REPUBLIC OF CHINA