ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD 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

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