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

Product Service

EC Certificate

Production Quality Assurance

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

No. G2 11 10 78476 002

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

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.: SH1171701

Valid from: 2019-12-13
Valid until: 2024-12-12

507679

Date, 2019-12-15

Hans-Heiner Junker

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

Digitally signed by Potînga Stela
Date: 2023.02.06 10:28:03 EET
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Facility(ies):

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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