ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

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 063744 0018 Rev. 02

Manufacturer:

Xiamen Compower Medical Tech. Co., Ltd.
Unit 301, No.16, Xianghong Road
Xiang'an Torch Industrial Zone
361101 Xiamen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Silicone/SEBS/PVC Manual Resuscitators (Including Mask, Positive End-Expiratory Pressure Valve, Oxygen Tube, Reservoir Bag, Mouth opener, Oropharyngeal Airway, Manometer), Resuscitation Mask, Continuous Positive Airway Pressure Mask/Non-invasive Ventilation Mask, Simple Oxygen Mask, Venturi Mask, Non-Rebreathing Mask, Aerosol Mask w/Nebulizer, Breathing Circuit (Including Mask, Elbow Connector, Y Piece, Corrugate Tubing, Collapsible Tubing, Water Trap, Straight Connector, HMEF), Anesthesia Circuit (Including Mask, Elbow Connector w/Luer Port & Cap, Y Piece, Corrugate Tubing, Collapsible Tubing, Straight Connector, Breathing Bag, Bacterial Filter, Gas Sampling Line), Anesthesia Mask, Breathing Filter for Single Use

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G2 063744 0018 Rev. 02

Report No.: SH20176EXT01
Valid from: 2020-11-04
Valid until: 2024-05-26
Date, 2020-11-04

Christoph Dicks
Head of Certification/Notified Body

Signed by /
Podpisano przez:

EZETEL POZNAŃ

Robert Kozłowicz

Date / Data:
2023-01-27 10:43

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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