



Benannt durch/Designated by
Zentralstelle der Länder
für Zulassungsverfahren für
Medizinprodukte und
Medizinprodukte
71.6-65-244-10.08



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 063744 0018 Rev. 01

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. See also notes overleaf.

Report No.: SH1917614
Valid from: 2019-08-26
Valid until: 2022-09-30

Date, 2019-08-26

Stefan Preiß
Head of Certification/Notified Body

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General quality inspected by
Zentrale der Länder
für Gesundheitsschutz
bei Medizinischen und
Medizinprodukten
www.bfarn.de
ZLG-BS-244. J.D. 08



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No. G2 063744 0018 Rev. 01

Facility(ies):

Xiamen Compower Medical Tech. Co., Ltd.
Unit 201, No.16, Xianghong Road, Xiang'an Torch Industrial Zone,
361101 Xiamen, PEOPLE'S REPUBLIC OF CHINA

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