Certificate

Quality Management System EN ISO 13485:2016

Registration No.:

SX 2375149-1

Certificate Holder:

Xiamen Compower Medical Tech. Co., Ltd.

Unit 301, No.16, Xianghong Road, Xiang'an Torch Industrial Zone,

361101 Xiamen P.R. China

Scope:

Design and Development, Manufacture and Distribution of Silicone Manual Ventilation Balloons, PVC Manual Ventilation Balloons, Oxygen Tubes, Reservoir Bags, Resuscitation Masks, Reusable Anesthesia Masks, Continuous Positive Airway Pressure Masks/Non-invasive Ventilation Masks, Simple Oxygen Masks, Venturi Masks, Non-Rebreathing Masks, Nose Clips, Anesthesia Masks, Silicone CPAP Masks for single patient reused, Oropharyngeal Airways, Mouth

Openers

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No .:

10920784-120

Effective date:

2023-10-13

Expiry date:

2026-10-12

Issue date:

2023-10-13

This certificate can be validated on https://www.certipedia.com

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany





TÜV Rheinland LGA Products GmbH • 51105 Köln

Xiamen Compower Medical Tech. Co., Ltd. Unit 301, No.16, Xianghong Road, Xiang'an Torch Industrial Zone, 361101 Xiamen P.R. China Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date October 13, 2023

Application for: QMS

Certificate No.: SX 2375149-1 Requirement: EN ISO 13485:2016

Dear Madame or Sir,

Your Quality Management System has been audited and fulfills the above-mentioned requirement.

Enclosed please find the certificate No. SX 2375149-1.

Best regards,

Wenxiang Zhang Certification body



TÜV Rheinland LGA Products GmbH

Am Grauen Stein 51105 Köln Germany

Headquarter

Tillystraße 2 90431 Nuremberg

Board of Management

Dipl.-Ing. Jörg Mähler, Spokesman

Dipl.-Kfm. Dr. Jörg Schlösser

Nuremberg HRB 26013 VAT No.: DE 811835490

Chairman of the Supervisory Board

Dr. Michael Fübi