

# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.	SX 2100418-1
Certificate Holder	GaleMed Corporation No. 87, Li-Gong 2nd Road, Wu-Jia, I-Lan 268 Taiwan
Scope	Design and Development, Manufacture and Distribution of Masks, Airbags, Connectors and Tubings, Manual Resuscitator Sets, Nebulizer Jets, Humidifier Chambers, CPAP Warmers, Bubble PAP Valves, Pressure Gauges, Percussors, Airway Management Kits, Spirometries for the area of anaesthesiology and Lung Simulators

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.	48219035-025
Effective date	2023-09-06
Expiry date	2026-09-05
Issue date	2023-09-06
Replaces certificate SX 2100418-1 issued 2022-12-09	

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



Samuel Qin  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

© TÜV, TÜV and TÜV are registered trademarks. Utilisation and application requires prior approval.