

Certificate

Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 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

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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.: 48302319-110

Effective date: 2026-09-06

Expiry date: 2029-09-05

Issue date: 2026-08-24

Replaces certificate SX 2100418-1 issued 2023-09-06



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