Certificate

Certificate No.:	MD 2100418-1-1
Manufacturer:	**GaleMed Corporation** No. 87, Li-Gong 2nd Road, Wu-Jia, I-Lan 268 Taiwan
REPs Facility ID:	F008359
Certification criteria:	ISO 13485:2016 Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009 Canada Medical Devices Regulations – Part 1 – SOR 98/282 Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
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

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	48274709-050
Issue Date:	2025-09-03
Effective Date:	2025-09-03
Expiry Date:	2028-09-02

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Samuel Qin
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com
or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, USA
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