

Certificate

Certificate No.: MD 2058519-1

Manufacturer: **GaleMed (Xiamen) Co., Ltd.**
Xiamen Area of China (Fujian)
Pilot Free Trade Zone,
39, Section 3, Haijing East Road
361026 Fujian Province
P.R. China

REPs Facility ID: F003720

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, Bubble PAP Valves, Pressure
Gauges, 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.: 10920547-100

Issue Date: 2022-08-17

Effective Date: 2022-08-17

Expiry Date: 2025-08-16



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

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9108641245?locale=en
or calling 1-888-743-4652.

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The scope of certification includes the following additional sites:

No.	Location	Scope
/01	GaleMed (Xiamen) Co., Ltd. Xiamen Area of China (Fujian) Pilot Free Trade Zone, 39, Section 3, Haijing East Road 361026 Fujian Province P.R. China REPs Facility ID: F003720	Activities related to Design and Development, Manufacture and Distribution
/02	GaleMed (Xiamen) Co., Ltd. Xiamen Area of China (Fujian) Pilot Free Trade Zone, 35, Section 2, Haijing East Road 361026 Fujian Province P.R. China REPs Facility ID: F003720	Activities related to Manufacture

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