Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 2058519-1
Certificate Holder:	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
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 and 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.:	10924085-100
Effective date:	2024-06-22
Expiry date:	2027-06-21
Issue date:	2024-06-17

Replaces certificate SX 2058519-1 issued 2022-06-15

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

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

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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

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DMP:2016-05-20-244419 V7.0

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EN ISO 13485:2016

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Xiamen Area of China (Fujian)
Pilot Free Trade Zone,
39, Section 3, Haijing East Road
361026 Fujian Province
P.R. China

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o 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	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 and Spirometries for the area of anaesthesiology and Lung Simulators
/02	c/o 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	Manufacture of Masks, Airbags, Connectors and Tubings, Manual Resuscitator Sets, Humidifier Chambers, Pressure Gauges and Spirometries for the area of anaesthesiology and Lung Simulators

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