

# Certificate

**Quality Management System**  
**EN ISO 13485:2016**

Registration No.: SX 2058519-1

Organization: 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

**TÜVRheinland**<sup>®</sup>

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.: 238540535-025  
Effective date: 2022-06-15  
Expiry date: 2024-06-21  
Issue date: 2022-06-15



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TÜV Rheinland LGA Products GmbH  
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The scope of certification also covers the following:

No.	Facility	Scope
/01	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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