



MINISTRY OF HEALTH AND WELFARE
REPUBLIC OF CHINA (TAIWAN)

Issue Date: August 18, 2022

No: MN001519

QMS Certificate

This is to certify that the quality management system of:

The Medical Device Manufacturer : GaleMed Corporation

Address : No. 87, Li-gong 2nd Rd., Chengxing Vil., Wu-jia Township, I-lan County, Taiwan
(R.O.C.)

QMS Number : QMS0053

Valid Until : April 7, 2025

This Certificate is applicable to : Medical Devices Listed in the Attachment of QMS
Certificate (QMS0053/No: MN001519).

The above-mentioned manufacturer, in accordance with Paragraph 2, Article 22 of the Medical Device Act, has been inspected and found to be in compliance with the Medical Device Quality Management System Regulations requirements (**based on ISO 13485:2016**). This certificate is hereby issued pursuant to Article 9 of the Regulations Governing the Inspection of the Medical Device Quality Management System and the Issuance of the Manufacturing license.

Signed by

Shou-Mei Wu

Director General
Food and Drug Administration
Under the delegated authority of
Jui-Yuan Hsueh, M.D., LL.M., Minister
Ministry of Health and Welfare
Republic of China (Taiwan)

MN 001519

Attachment of QMS Certificate (QMS0053/No: MN001519)

Manufacturer : GaleMed Corporation

Address : No. 87, Li-gong 2nd Rd., Chengxing Vil., Wu-jia Township, I-lan County,
Taiwan (R.O.C.)

No.	Medical Devices	Activities
1	Continuous Ventilator and Accessories	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
2	Incentive Spirometer	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
3	Powered Percussor	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
4	Powered Emergency Ventilator	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
5	Manual Emergency Ventilator	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
6	Nonrebreathing Valve	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
7	Nebulizer	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
8	Respiratory Gas Humidifier	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
9	Peak-Flow Meter for Spirometry	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
10	Breathing Circuit Bacterial Filter	Design, Manufacture, Packaging, Labeling, Final Inspection and Release

11	Gas Pressure Gauge	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
12	Electrosurgical Cutting and Coagulation Device and Accessories	Design, Packaging, Labeling, Final Inspection and Release
13	Positive End Expiratory Pressure Breathing Attachment	Design, Manufacture, Packaging, Labeling, Final Inspection and Release

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