



MINISTRY OF HEALTH AND WELFARE
REPUBLIC OF CHINA (TAIWAN)

Issue Date: January 26, 2024

No: MN001905

QMS Certificate

This is to certify that the quality management system of:

The Medical Device Manufacturer : GREAT GROUP MEDICAL CO., LTD.

Address : No. 168, Xingong 2nd Rd., Shalun Vil., Tianshong Township, Changhua County,
Taiwan (R.O.C.)

QMS Number : QMS1010

Valid Until : December 22, 2026

This Certificate is applicable to : Medical Devices Listed in the Attachment of QMS
Certificate (QMS1010/No: MN001905).

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.

Shou-Mei Wu

Signed by _____

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)

MN001905

Attachment of QMS Certificate (QMS1010/No: MN001905)

Manufacturer : GREAT GROUP MEDICAL CO., LTD.

Address : No. 168, Xingong 2nd Rd., Shalun Vil., Tianzhong Township, Changhua County,
Taiwan (R.O.C.)

No.	Medical Devices	Activities
1	Airway Connector	Design, Packaging, Labeling, Final Inspection and Release
2	Ventilator Tubing	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
3	Nasal Oxygen Cannula	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
4	Filter for Medical Gas Yoke Assembly	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
5	Anesthesia Breathing Circuit	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
6	Artificial Nose	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
7	Water Trap	Design, Packaging, Labeling, Final Inspection and Release
8	Respiratory Gas Humidifier Chamber	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
9	Breathing Circuit Bacterial Filter(Sterile)	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
10	Respiratory Gas Humidifier	Design, Manufacture, Packaging, Labeling, Final Inspection and Release
11	Patient Transducer and Electrode Cable (Including Connector)	Design, Packaging, Labeling, Final Inspection and Release
12	Positive End Expiratory Pressure Breathing Attachment	Design, Manufacture, Packaging, Labeling, Final Inspection and Release

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