

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1676663-1

Organization: Vincent Medical Manufacturing
Co., Ltd.
Flat/RM B2, 7/F., Hang Fung
Industrial Building, Phase 2
2G Hok Yuen Street
Hung Hom, Kowloon
Hong Kong

Scope: Manufacture of Sterile and Non-sterile Plastic Medical Devices including Contrast Media Infusion Set, Disposable Syringe, Connector Tubing and Intravenous Administration Set (Burette); Pressure Infusors; Design and Development, Manufacture and Distribution of Respiratory Medical Devices and Circumcision Devices, Bubble CPAP Systems, Sterile Heat and Moisture Exchange Filters, Nasal Cannulas, Electronic Air Oxygen Blenders, High Flow Heated Respiratory Humidifiers. Provision of Ethylene Oxygen Sterilization Service in accordance with EN ISO 11135:2014
Manufacture and Final Inspection of Rehabilitation Devices and Modules
Contract Manufacture of Forced Air Warming Blankets for Medical Use and Sterile Hand Controller of Angiographic Injectors

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.: 10917950-100
Effective date: 2021-05-11
Expiry date: 2024-04-16
Issue date: 2021-05-11



Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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The scope of certification also covers the following:

No.	Facility	Scope
/01	Vincent Medical Manufacturing Co., Ltd. Flat/RM B2, 7/F., Hang Fung Industrial Building, Phase 2 2G Hok Yuen Street Hung Hom, Kowloon Hong Kong	License holder only

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Flat/RM B2, 7/F., Hang Fung Industrial Building, Phase 2
2G Hok Yuen Street
Hung Hom, Kowloon
Hong Kong

The scope of certification also covers the following:

/02 Vincent Medical (Dong Guan) Manufacturing Co., Ltd.
45-46 ShaBu Industrial Zone
Qiao Long District, Tang Xia Town
Dong Guan City
523730 Guangdong Province
P.R. China

Manufacture of Sterile and Non-sterile Plastic Medical Devices including Contrast Media Infusion Set, Disposable Syringe, Connector Tubing and Intravenous Administration Set (Burette); Pressure Infusors; Design and Development, Manufacture and Distribution of Respiratory Medical Devices and Circumcision Devices, Bubble CPAP Systems, Sterile Heat and Moisture Exchange Filters, Nasal Cannulas, Electronic Air Oxygen Blenders, High Flow Heated Respiratory Humidifiers; Provision of Ethylene Oxygen Sterilization Service in accordance with EN ISO 11135:2014
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