



**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60146949 0001

**Report No.:** 17046778 013

**Manufacturer:** 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

**Products:** Medical Devices  
  
(see attachment for site and products included)

Replaces Approval, Registration No.: HD 60143042 0001

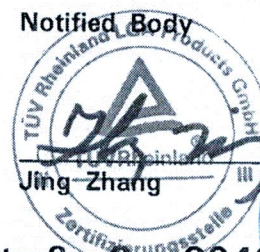
**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2020-02-13

**Date:** 2020-02-13

Notified Body



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC  
concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60146949 0001  
**Report No.:** 17046778 013

**Manufacturer:** 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

**Products:**

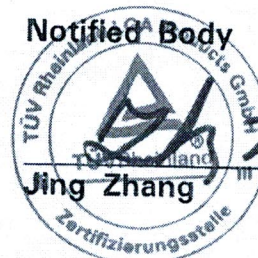
- Respiratory Medical Devices  
Products: Ventilation Breathing Circuits, Anaesthesia  
Breathing Circuits, Breathing Circuit Components and  
Accessories, Breathing Bags; Breathing System Filters with  
Bacterial/Viral Filters, HEPA Filters, Heat and Moisture  
Exchanges Filters, Water Traps, Corrugated Tubings, Reusable  
Hytrel Tubings, Coaxial Circuits, Heated Breathing Circuits,  
Face Masks, Smoothbore Breathing Circuits, Humidifiers,  
Humidification Chambers, Ultrasonic Nebulizers, CPAP Patient  
Interface, Bubble CPAP Systems, Sterile Heat and Moisture  
Exchange Filters, Nasal Cannulas, Electronic Air Oxygen  
Blenders, High Flow Heated Respiratory Humidifiers.

**Site included:**

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



**Date:** 2020-02-13





# Certificate



## Quality Management System EN ISO 13485:2016

Registration No.: SX 1676663-1

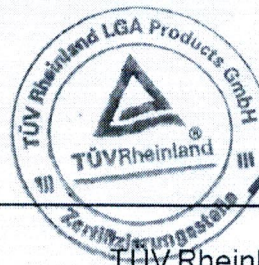
Organization: Vincent Medical Manufacturing Co., Ltd.  
Flat/RM B2, 7/F., Hang Fung  
Industrial Building, Phase 2  
2G Hok Yuen Street  
Hung Hom, Kowloon  
Hong Kong

Scope: Manufacture of Sterile and Non-sterile Plastic Medical Devices including Contrast Media Infusion Sets, Disposable Syringes, Connector Tubing and Intravenous Administration Sets (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.: 10921646-100  
Effective date: 2023-01-12  
Expiry date: 2024-04-16  
Issue date: 2023-01-12



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





# 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

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o 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

Report No.: 10921646-100  
Effective date: 2023-01-12  
Expiry date: 2024-04-16  
Issue date: 2023-01-12



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



# Certificate



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

Registration No.: SX 1676663-1


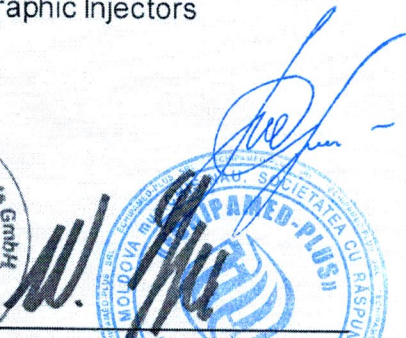

Organization: Vincent Medical Manufacturing Co., Ltd.  
Flat/RM B2, 7/F., Hang Fung  
Industrial Building, Phase 2  
2G Hok Yuen Street  
Hung Hom, Kowloon  
Hong Kong

The scope of certification also covers the following:

- /02 c/o Vincent Medical (Dong Guan) Manufacturing Co., Ltd.  
11 ShaBu Street, Qiao Long District,  
Tang Xia Town, 523730 Dong Guan City,  
Guangdong Province,  
P.R. China
- Manufacture of Sterile and Non-sterile Plastic Medical Devices including Contrast Media Infusion Sets, Disposable Syringes, Connector Tubing and Intravenous Administration Sets (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;  
Distribution of 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

Report No.: 10921646-100  
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Dipl.-Ing. W. Hsu  
TUV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



# 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

The scope of certification also covers the following:

/03	c/o Vincent Medical (Dongguan) Technology Company Limited RM 101 and 201, Block 10, 1st Taoyuan Road, Songshan Lake Zone, Dongguan, 523808 Guangdong P.R. China	Design and Development, Manufacture of Active Respiratory Medical Devices
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Report No.: 10921646-100  
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