

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

**Registration No.:** HD 60114699 0001

**Report No.:** 17046778 004

**Manufacturer:** Vincent Medical Manufacturing  
Co., Ltd.  
Flats B2 & C2, 7/F., Hang Fung  
Industrial Building, Phase 2  
2G Hok Yuen Street  
Hung Hom, Kowloon  
Hong Kong

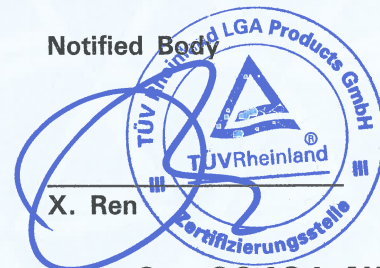
**Products:** Medical Devices  
  
(see attachment for site and products included)  
  
Replaces Approval, Registration No.: HD 60100640 0001

**Expiry Date:** 2020-04-16

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:** 2016-12-21

**Date:** 2016-12-21



**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**

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**Report No.:** 17046778 004

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Flats B2 & C2, 7/F., Hang Fung  
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**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  
Hyrel Tubings, Coaxial Circuits, Heated Breathing Circuits,  
Face Masks, Smoothbore Breathing Circuits, Respiratory  
Humidification systems (Humidifiers, Humidification  
Chambers), Ultrasonic Nebulizers, CPAP Patient Interface  
- Circumcision Devices

**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.

Design and Development, Manufacture of Respiratory Medical  
Devices and Circumcision Devices

**Date:** 2016-12-21

**Notified Body**

