

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

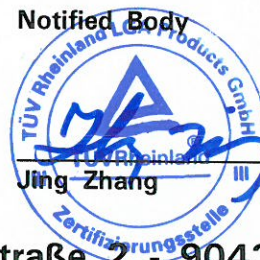
Expiry Date: 2024-05-26

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

