



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:

10/020 d 04.08 @ TUV, TUEV and TUV are registered trademarks, Utilication and application requires prior approval

2020-02-13

Date:

2020-02-13

TÜV Rheinland LGA Products GmbH - Tillystraße 2 run 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.



LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.: Report No .:

HD 60146949 0001 17046778 013

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Co., Ltd.

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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 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

0,000 d. 04.08. 8 TÜV, TUEV and TUV are registered trademarks, Utilisation and application requires prior approval

