

To whom it may concern

Manufacturer's Authorization

Date: March 1st 2024

We Vincent Medical Manufacturing Co., Ltd., who are official manufacturers of respiratory care, Neonatal care, Anaesthesia medical device and consumables, having factories at Flat/RM B2, 7/F., Hang Fung Industrial Building, Phase 2 2G Hok Yuen Street Hung Hom, Kowloon Hong Kong, do hereby authorize

“ECHIPAMED-PLUS” SRL
 str. Valea Trandafirilor 24 “B”, of. 2-7
 MD-2001, Chisinau
 Republic of Moldova

to submit a bid by the **Tender No. ocds-b3wdp1-MD-1707227476464 (MTender ID) /21166970 (Achizitii.md ID) of March 2nd, 2024, organized by the “Institute of Mother and Child”, the purpose of which is to provide the following Goods, manufactured by us**

Catalogue P/N	Description
50449100	Adult Anaesthetic Breathing Circuits\2.4m
51005286	nCPAP Generator + S/M/L Nasal prong
51007960	Single limb, 2pcs PVC tubing, generator connector, VHC10
50421700	High performance Viral / bacterial respiratory filter/BSF 202
50426500	Pediatric anesthesia breathing circuit\1.5m\expandable\bi wye, GS elbow, 1L breathing bag, BSF201, 1.0m spare limb
51005304	nCPAP Infant Bonnet\22-24cm

and to subsequently negotiate and sign the Contract, as well as to perform installation and after sales Service.

Vincent Medical Manufacturing Co., Ltd.



Amanda Hu

Sales & Marketing Manager





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

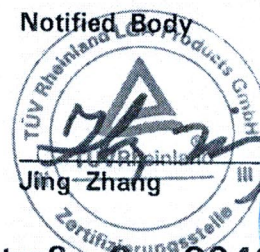
Expiry Date: 2024-05-26

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:

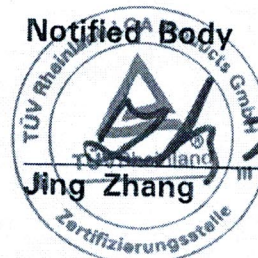
- Respiratory Medical Devices
Products: Ventilation Breathing Circuits, Anaesthesia
Breathing Circuits, Breathing Circuit Components and
Accessories, Breathing Bags; Breathing System Filters with
Bacterial/Viral Filters, HEPA Filters, Heat and Moisture
Exchanges Filters, Water Traps, Corrugated Tubings, 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

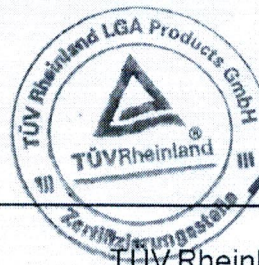
Organization: Vincent Medical Manufacturing Co., Ltd.
Flat/RM B2, 7/F., Hang Fung
Industrial Building, Phase 2
2G Hok Yuen Street
Hung Hom, Kowloon
Hong Kong

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

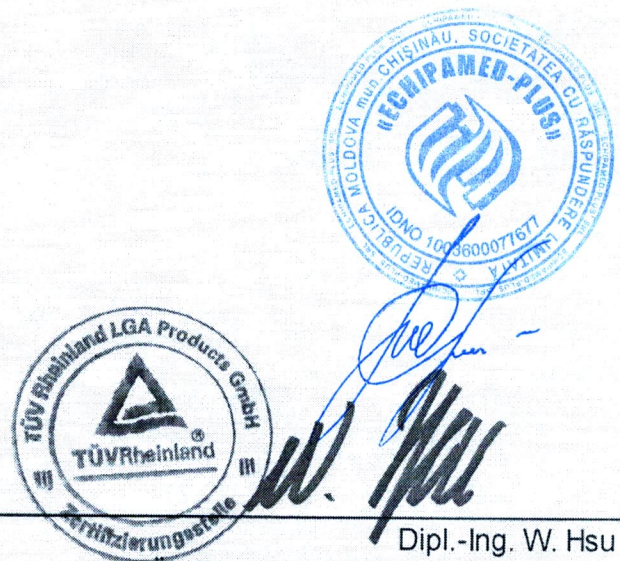
Registration No.: SX 1676663-1

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
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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


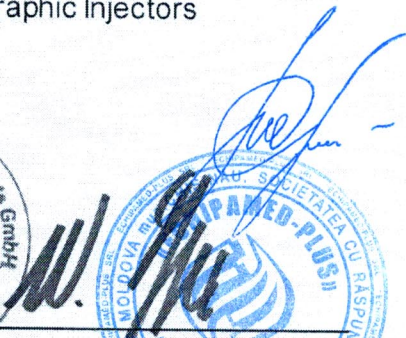

Organization: Vincent Medical Manufacturing Co., Ltd.
Flat/RM B2, 7/F., Hang Fung
Industrial Building, Phase 2
2G Hok Yuen Street
Hung Hom, Kowloon
Hong Kong

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

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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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