EC Certificate

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

Registration No.: HD 60134007 0001

Report No.: 17051410 009

Manufacturer:
Vega Technologies Inc.
11F-13, No. 100 Chang Chun Road
Taipei 104
Taiwan

Products:
Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60117935 0001

Expiry Date: 2024-01-16

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: 2019-01-17

Date: 2019-01-09

Notified Body

S. Liu

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60134007 0001
Report No.: 17051410 009

Manufacturer:
Vega Technologies Inc.
11F-13, No. 100 Chang Chun Road
Taipei 104
Taiwan

Products:

- Continuous Positive Airway Pressures (CPAP)
- Nebulizers
- Digital Thermometers
- Electric Suction Units
- Heated Humidifiers

Site included:

Vega Technologies Inc.
Yang-Wu District, Da Lang Town, Dong Guan City,
Guang Dong Province, China

Date: 2019-01-09

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

S. Liu