EC Certificate

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

Registration No.: HD 60129751 0001

Report No.: 50130549 001

Manufacturer:
Apex Medical Corp.
No. 9, Min Sheng St.
Tu-Cheng, New Taipei City 23679
Taiwan

Products:
Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60102968 0001

Expiry Date: 2023-06-25

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: 2018-06-26

Date: 2018-06-19

Notified Body

X. Ren

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60129751 0001
Report No.: 50130549 001

Manufacturer:
Apex Medical Corp.
No. 9, Min Sheng St.
Tu-Cheng, New Taipei City 23679
Taiwan

Products:

- Therapeutic Air Mattresses
- Continuous Positive Airway Pressure(CPAP) & Heated Humidifiers
- Continuous Positive Airway Pressure(CPAP) Masks with Tubings
- Nebulizers and Nebulizer Kits
- Transcutaneous Electrical Nerve Stimulation(TENS) / Electronic Muscle Stimulator(EMS)
- Suction Pumps
- Negative Pressure Wound Therapy Systems (NPWT)

Site included:

Apex Medical (Kunshan) Corp.
No. 1368, Zi Zhu Rd., Kunshan Kai Fa Hi-Tech,
Kunshan City, JiangSu Sheng, China

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2018-06-19

X. Ren