

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

Registration No.: HD 60085553 0001

Report No.: 10040682 001

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

Products: Medical Devices
(see attachment for products and sites included)
Replaces Approval, Registration No.: HD 60080171 0001

Expiry Date: 2018-06-25

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: 2013-07-02

Date: 2013-07-02



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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60085553 0001
Report No.: 10040682 001

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

Products:

- Therapeutic Air Mattresses
- Nebulizers
- Nebulizer Kits
- T.E.N.S./EMS Devices
- CPAP & Heated Humidifiers
- CPAP Masks with Tubings
- Suction Pumps
- Intermittent Pneumatic Compression Devices
and Compression Sleeves
- Negative Pressure Wound Therapy Systems

TÜVRheinland[®]

Date: 2013-07-02



Notified Body

X. Ren

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60085553 0001
Report No.: 10040682 001

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

Sites included:

Apex Medical Corp.
No. 9, Min Sheng St., Tu-Cheng, New Taipei City, 23679,
Taiwan, R.O.C.

Design, Development and Manufacture of Therapeutic Air
Mattresses, Nebulizers, Nebulizer Kits, T.E.N.S./EMS Devices,
CPAP & Heated Humidifiers, CPAP Masks with Tubing, Suction
Pumps, Intermittent Pneumatic Compression Devices and
Compression Sleeves, Negative Pressure Wound Therapy Systems

Apex Medical (Kunshan) Corp.
No. 1368, Zi Zhu Rd., Kunshan Kai Fa Hi-Tech,
Kunshan City, JiangSu Sheng, China
Manufacture of Therapeutic Air Mattresses, Nebulizers,
Intermittent Pneumatic Compression Devices and Compression
Sleeves

Apex Medical (Changhua) Corp.
No.121, Sec. 3, Zhongshan Rd., Dacun, Changhua 51542,
Taiwan, R.O.C.
Design, Development and Manufacture of Suction Pumps

Date: 2013-07-02



Notified Body

X Ren