

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Apex Medical Corp.
No. 9, Min Sheng St.
Tu-Cheng, New Taipei City 23679
Taiwan

has established and applies a quality management system for medical devices
for the following scope:

**Design, Development, Manufacture and Distribution
of Medical Devices
(see attachment for products and sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-06-26
Certificate Registration No.: SX 60129752 0001
An audit was performed. Report No.: 50130549 001
This Certificate is valid until: 2021-06-25

Certification Body



Date 2018-06-19



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60129752 0001
Report No.: 50130549 001

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

Scope:

Products:

- Therapeutic Air Mattresses, Compression Sleeves, Cushions and Pumps
- 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)
- Technical Aids for Disabled Persons

Certification Body



Date: 2018-06-19



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Certificate**

Registration No.: SX 60129752 0001
Report No.: 50130549 001

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

Scope: Sites included:

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

Design, Development, Manufacture and Distribution of
Therapeutic Air Mattresses, Compression Sleeves,
Cushions and Pumps, Continuous Positive Airway Pressure
(CPAP) & Heated Humidifiers, Continuous Positive Airway
Pressure (CPAP) Masks with Tubings, Nebulizers and Nebulizer
Kits, Negative Pressure Wound Therapy Systems (NPWT);
Design and Development and Distribution of Suction Pumps;
Distribution of Transcutaneous Electrical Nerve
Stimulation (TENS)/Electronic Muscle Stimulator (EMS),
Technical Aids for Disabled Persons

Certification Body



Date: 2018-06-19



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60129752 0001
Report No.: 50130549 001

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

Scope: Sites included:

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

Manufacture of Therapeutic Air Mattresses,
Compression Sleeves, Cushions and Pumps,
Nebulizers and Nebulizer Kits

Certification Body



Date: 2018-06-19

