

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



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TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/3, Rev. 0

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

Doc. 2/3, Rev. 0

Attachment to Certificate

Registration No.:

SX 60129752 0001

50130549 001

Organization:

Report No.:

Apex Medical Corp. No. 9, Min Sheng St.

Tu-Cheng, New Taipei City 23679

Taiwan

Scope:

Sites included:

Apex Medical Corp.

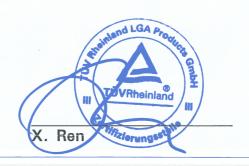
No. 9, Min Sheng St., Tu-Cheng, New Taipei City, 23679, Taiwan

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

Doc. 3/3, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

SX 60129752 0001 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

