

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Apex Medical Corp.
No. 9, Min Sheng St.
23679 Tu-Cheng, New Taipei City
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 13485:2012
EN ISO 13485:2012/AC:2012

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

Certificate Registration No.: SX 60078814 0001

An audit was performed. Report No.: 10022479 007

This Certificate is valid until: 24.06.2013

Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Date 22.11.2012



X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60078814 0001
Report No.: 10022479 007

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

Scope: Products:

- Air Mattresses, Compression Sleeves, Cushions and Pumps
- Nebulizers
- Nebulizer Kits
- CPAP & Heated Humidifiers
- CPAP Masks with Tubings
- T.E.N.S./EMS devices
- Technical Aids for Disabled Persons
- Suction Pumps
- Intermittent Pneumatic Compression Devices and Compression Sleeves
- Negative Pressure Wound Therapy Systems



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Certification Body

Date: 2012-11-22

X. Ren

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/3, Rev. 0

Attachment to
Registration No.: SX 60078814 0001
Report No.: 10022479 007

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

Scope: Apex Medical Corp.
No. 9, Min Sheng St., Tu-Cheng, New Taipei City, 23679,
Taiwan, R.O.C.
Design, Development, Manufacture and Distribution of
Air Mattresses, Compression Sleeves, Cushions and Pumps,
Nebulizers, Nebulizer Kits, CPAP & Heated Humidifiers,
CPAP Masks with Tubings, T.E.N.S./EMS devices, Technical
Aids for Disabled Persons, 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 Air Mattresses, Compression Sleeves, Cushions
and Pumps, Nebulizers, Intermittent Pneumatic Compression
Devices and Compression Sleeves



Date: 2012-11-22



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60078814 0001
Report No.: 10022479 007

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

Scope: Apex Medical (Changhua) Corp.
43 Hsinking 1st Rd., Peitou Industrial Park, Peitou,
Changhua Hsien, Taiwan, R.O.C.

Design, Development and Manufacture of Suction Pumps



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und Medizinprodukten
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