

**Business Stream Products
Certification Department**

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Mr. Kuo Chang Lee
Merits Health Products Co., Ltd.
No. 18, Jingke Rd.
Nantun Dist.,
TAICHUNG CITY 40852
TAIWAN

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date March 15, 2019

Application for : QMS
Certificate No. : SX 60135519 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Mr. Lee,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate
No. SX 60135519 0001.

Kind regards

Certification body



M.Sc. M. Aihara

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
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Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Merits Health Products Co., Ltd.
No. 18, Jingke Rd.
Nantun Dist.,
Taichung City 40852
Taiwan

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

**Design and Development, Manufacture and Distribution of
Medical Devices**
(see attachment for products and additional site 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: 2019-03-15
Certificate Registration No.: SX 60135519 0001
An audit was performed. Report No.: 10044228 006
This Certificate is valid until: 2022-02-15

Certification Body



Date 2019-03-15



M.Sc. M. Aihara

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60135519 0001
Report No.: 10044228 006

Organization: Merits Health Products Co., Ltd.
No. 18, Jingke Rd.
Nantun Dist.,
Taichung City 40852
Taiwan

Scope:

Products:

Oxygen Concentrators, Electric Scooters, Power Wheelchairs,
Manual Wheelchairs, Bathlifts, Electric Beds, Ambulatory
Aids, Bathroom Aids, Stair Lifts and Stair Climbers for
disabled person

Site included:

Merits Healthcare Industries (Suzhou) Co., Ltd.
No. 29, Fuzhou Road, TaiCang City,
JiangSu Province 215411, China

Design and Development, Manufacture and Distribution of
Electric Scooters, Power Wheelchairs, Manual Wheelchairs,
Electric Beds, Ambulatory Aids and Bathroom Aids

Certification Body



Date: 2019-03-15



M.Sc. M. Aihara