

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
OMRON DALIAN Co., Ltd.
No. 3, Song Jiang Road
Economic and Technical
Development Zone
Dalian 116600
China

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 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: 2018-09-29
Certificate Registration No.: SX 60130629 0001
An audit was performed. Report No.: 15049200 008
This Certificate is valid until: 2020-06-15

Certification Body



Date 2018-09-29



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 60130629 0001
Report No.: 15049200 008

Organization: OMRON DALIAN Co., Ltd.
No. 3, Song Jiang Road
Economic and Technical
Development Zone
Dalian 116600
China

Scope:

Products:

- Electronic Sphygmomanometers
- Electronic Clinical Thermometers
- Infrared Clinical Thermometers
- Electrical Therapy Devices
(Electroanalgesic Transcutaneous Stimulators)
- TENS Devices
- Pedometers
- Inhalers
- Nebulizers
- Body Fat Analyzers
- Sleeping Monitors
- Oxygen Generators
- Cardiovascular Profiling Systems

Site included:

OMRON DALIAN Co., Ltd.
No. 28, Dong Bei Er Street, Economic & Technical
Development Zone, Dalian 116600, P.R. China
Design and Development, Manufacture and Distribution of
the a.m. products

Certification Body



Date: 2018-09-29


Allen Chen

