

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo
Terado-cho, Muko
Kyoto 617-0002
Japan

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

**Design and Development, Manufacture, Distribution
and Servicing of Medical Devices for diagnosis and therapy
(see attachments for products and additional 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: 2017-08-28
Certificate Registration No.: SX 60122242 0001
An audit was performed. Report No.: 12031342 001
This Certificate is valid until: 2020-08-27

Certification Body



Date 2017-08-22




M.Sc. M. Aihara

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
Certificate**

Registration No.: SX 60122242 0001
Report No.: 12031342 001

Organization: OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo
Terado-cho, Muko
Kyoto 617-0002
Japan

Scope:

Products included:

- Electronic Sphygmomanometers
- Blood Pressure Monitors
- Clinical Electronic Thermometers
- Ear Thermometers
- Infrared Forehead Thermometers
- Inhalers
- Nebulizers
- Electroanalgesic Transcutaneous Stimulators
- Electroanalgesic Transcutaneous Stimulators Electrodes
- Electrocardiographs
- Cardiovascular Profiling Systems
- Body Composition Analyzers
- Body Fat Analyzers

Certification Body



Date: 2017-08-22


M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60122242 0001
Report No.: 12031342 001

Organization: OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo
Terado-cho, Muko
Kyoto 617-0002
Japan

Scope: Sites included:

OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo, Terado-cho, Muko, Kyoto, 617-0002 Japan

Scope:
Activities related to Design, Development, Manufacture,
Distribution and Servicing

OMRON HEALTHCARE Co., Ltd.
Matsusaka Factory
1855-370, Kubo-cho, Matsusaka-shi, Mie, 515-8503 Japan

Scope:
Activities related to Manufacture, Distribution and
Servicing

Certification Body



Date: 2017-08-22


M.Sc. M. Aihara