

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60100990 0001

**Report No.:** 12031342 007

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

**Products:** (see attachments for products and additional site included)  
Replaces approval, registration no. HD 60100203 0001

**Expiry Date:** 2024-03-21

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2019-03-22

**Date:** 2019-03-22



**Notified Body**



**M.Sc. M. Aihara**

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60100990 0001  
**Report No.:** 12031342 007

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

**Products included:**

- Electronic Sphygmomanometers
- Clinical Electronic Thermometers
- Ear Thermometers
- Infrared Forehead Thermometers
- Nebulizers
- Electroanalgesic Transcutaneous Stimulators
- Electroanalgesic Transcutaneous Stimulation Electrodes
- Cardio Vascular Profiling Systems
- Wheeze Detectors

**Date:** 2020-01-28



**Notified Body**

*M. Aihara*

**M.Sc. M. Aihara**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60100990 0001

**Report No.:** 12031342 001

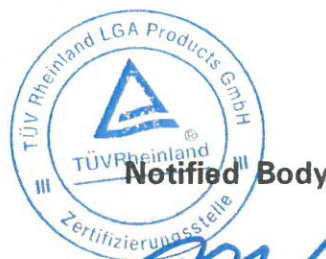
**Manufacturer:** OMRON HEALTHCARE Co., Ltd.  
53, Kunotsubo,  
Terado-cho, Muko  
Kyoto,  
617-0002 Japan

**Sites included:**

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

**Scope:**

Manufacturing of Electronic Sphygmomanometers, Clinical  
Electronic Thermometers, Ear Thermometers, Infrared Forehead  
Thermometers, Nebulizers, Electroanalgesic Transcutaneous  
Stimulators, Electroanalgesic Transcutaneous Stimulation  
Electrodes, Cardio Vascular Profiling Systems



**Date:** 2020-01-28

  
**M.Sc. M. Aihara**