

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

**Registration No.:** HD 60100203 0001

**Report No.:** 12022694 001

**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 60041154 0001

**Expiry Date:** 2019-09-16

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:** 2015-03-05

**Date:** 2015-03-05

Notified Body  
TÜV Rheinland LGA Products GmbH  
D. Swiatko  


**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**

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53, Kunotsubo  
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**Products included:**

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

**Date:** 2015-03-05

**Notified Body**



**D. Swiatko**



The stamp is circular with the TÜVRheinland logo in the center. The text around the logo reads "TÜV Rheinland LGA Products GmbH" at the top and "Zertifizierungsstelle" at the bottom.

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

Doc. 2/2, Rev. 1

**Attachment to  
Certificate**

**Registration No.:** HD 60100203 0001  
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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

Manufacture

**Date:** 2015-04-09

**Notified Body**



**D. Swiatko**



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