

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**

Registration No.: HD 60100203 0001

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Manufacturer: OMRON HEALTHCARE Co., Ltd.
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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



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Registration No.: HD 60100203 0001
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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



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