

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

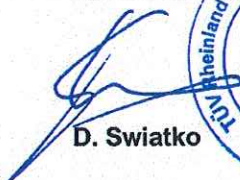
Products: (see attachments for products and additional site included)
Replaces approval, registration no. HD 60041154 0001

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

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

Doc. 1/2, Rev. 0

**Attachment to
Certificate**

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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

Doc. 2/2, Rev. 1

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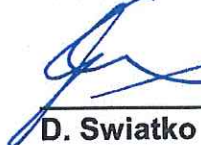
Sites included:

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

