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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

M. Aihara

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.

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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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2019-03-22

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev. 0

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

Manufacture

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Notified Body

Date: 2019-03-22

M.Sc. M. Aihara