

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60137913 0001

Report No.: 12031342 008

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. DD 60100204 0001

Expiry Date: 2024-03-21

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-03-22

Date: 2019-03-22



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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60137913 0001
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Kyoto,
617-0002 Japan

Products included:

- Electrocardiographic Intermittent Event Recorders

For the following medical devices the scope covers only the aspects of manufacture concerned with conformity of products with the metrological requirements:

- Body Composition Analyzers
- Body Fat Analyzers



Notified Body

Date: 2019-03-22


M.Sc. M. Aihara

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LGA Products GmbH
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Manufacturer: OMRON HEALTHCARE Co., Ltd.
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Terado-cho, Muko
Kyoto, 617-0002
Japan

Site included:

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

Manufacture



Notified Body

M. Aihara

Date: 2019-03-22

M.Sc. M. Aihara