TÜVRheinland®

EC Certificate

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

Registration No.: DD 60100204 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. DD 60041155 0001

Expiry Date: 2019-09-16

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: 2015-03-05

Date: 2015-03-05

Notified Body

D. Swiatko

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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.

TÜVRheinland®

Doc. 1/2, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60100204 0001
Report No.: 12022694 001

Manufacturer: OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo
Terado-cho, Muko
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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

D. Swiatko

Date: 2015-04-09

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60100204 0001
Report No.: 12022694 001

Manufacturer: OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo
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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

D. Swiatko

Date: 2015-03-05