

**APPROVAL**  
**EC Directive 93/42/EEC Annex V, Article 3**  
**Quality Assurance System Production**

**Registration No.:** DD 60041392 0001

**Report No.:** 12018163 001



**Manufacturer:** OMRON HEALTHCARE Co., Ltd.  
24, Yamanouchi  
Yamanoshita-cho, Ukyo-ku  
KYOTO 615-0084  
JAPAN

**Scope:** Manufacture of Medical Devices  
  
(See attachments for products and additional sites included)  
  
Replaces Approval, Registration No. DD 60034796 0001

**Date of Expiry:** 16.09.2016

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Date 17.10.2011

  
Notified Body  
  
Dipl.-Ing. S. Pane

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and  
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to**  
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KYOTO 615-0084  
JAPAN

**Scope:** Products included:  
- Electrocardiographs

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

**Date** 17.10.2011



**Certification Body**

  
**Dipl.-Ing. S. Pane**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to**  
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**Manufacturer:** OMRON HEALTHCARE Co., Ltd.  
24, Yamanouchi  
Yamanoshita-cho, Ukyo-ku  
KYOTO 615-0084  
JAPAN

**Scope:** Sites included:

OMRON HEALTHCARE Co., Ltd.  
24, Yamanouchi Yamanoshita-cho, Ukyo-ku, Kyoto  
615-0084 Japan

Tokyo Branch Office  
5-9-11, Kitashinagawa, Shinagawa-ku, Tokyo  
141-0001 Japan

Matsusaka Branch Office  
1855-370, Kubo-cho, Matsusaka-shi, Mie  
515-8503 Japan



**Certification Body**

**Date** 17.10.2011

  
**Dipl.-Ing. S. Pane**