

APPROVAL
EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60041154 0001

Report No.: 12018163 002

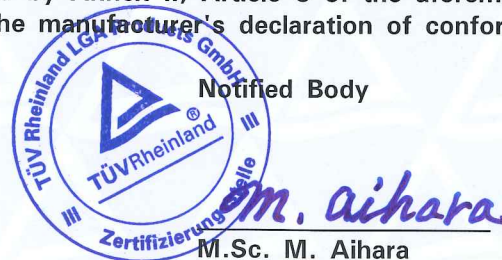
Manufacturer: OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo
Terado-cho, Muko
KYOTO, 617-0002
JAPAN

Scope: Design, Development and Manufacture of Medical Devices
(see attachments for products and additional sites included)
Replaces approval, registration no. HD 60041391 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 II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Date 18.10.2011



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
Registration No.: HD 60041154 0001
Report No.: 12018163 002

Manufacturer: OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo
Terado-cho, Muko
KYOTO, 617-0002
JAPAN

Scope: Products included:

- Electronic Sphygmomanometers
- Clinical Electronic Thermometers
- Ear Thermometers
- Nebulizers
- Electroanalgesic Transcutaneous Stimulators
- Electroanalgesic Transcutaneous Stimulation Electrodes
- Patient Monitors
- Cardio Vascular Profiling Systems

Date 18.10.2011



Certification Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: HD 60041154 0001
Report No.: 12018163 002

Manufacturer: OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo
Terado-cho, Muko
KYOTO, 617-0002
JAPAN

Scope: Sites included:

OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo, Terado-cho, Muko, Kyoto
617-0002 Japan

Tokyo Branch Office
2-3-13, Konan, Minato-ku, Tokyo
108-0075, Japan

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



Certification Body

Date 18.10.2011

M. Aihara
M.Sc. M. Aihara