

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

Registration No.: HD 60041391 0001

Report No.: 12018163 001

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

Scope: Design, Development and Manufacture of Medical Devices
(see attachments for products and additional sites included)
Replaces approval, registration no. HD 60018171 0001

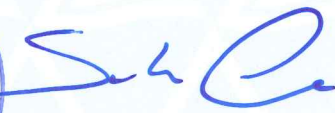
Date of Expiry: 16.09.2016

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.

Notified Body

Date 17.10.2011




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.



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

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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 17.10.2011



Certification Body


Dipl.-Ing. S. Pane

TÜV Rheinland
LGA Products GmbH
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Yamanoshita-cho, Ukyo-ku
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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

Date 17.10.2011



Certification Body


Dipl.-Ing. S. Pane