

APPROVAL

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

Registration No.: DD 60020977 0001

Report No.: 21134502 002



Manufacturer: OMRON Healthcare Europe B.V.
Kruisweg 577
2132 NA Hoofddorp
Netherlands

Scope: Production of medical devices
Products: see Attachment
Replaces Approval, Registration No.: DD 60004100 0001

Date of Expiry: 18.03.2013

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.

Cologne, 19.03.2008

Notified Body

Dipl.-Ing. I. Munkler


TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
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
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: DD 60020977 0001
Report No.: 21134502 002

Manufacturer: OMRON Healthcare Europe B.V.
Kruisweg 577
2132 NA Hoofddorp
Netherlands

Scope: Products:

- Nebulizers
- Electronic thermometers

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

- Spirometers

Cologne, 19.03.2008



Dipl.-Ing. I. Munkler