

# Certificate

The Certification Body of  
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices  
for the following scope:

**Equipping, marketing, incoming inspection,  
distribution and servicing of medical devices**  
**Products: see Attachment**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2003 + AC:2007**

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60020979 0001

An audit was performed. Report No.: 21134502 002

This Certificate is valid until: 18.03.2013



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-995.00.01-46

Cologne, 19.03.2008

Certification Body



Dipl.-Ing. I. Munkler

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

**Attachment to**  
**Registration No.:** SX 60020979 0001  
**Report No.:** 21134502 002

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

**Scope:** Products:

- Sphygmomanometers
- Nebulizers
- Electronic and infrared thermometers
- Spirometers
- Body fat analyzers
- Electroanalgesic transcutaneous stimulators
- Electrocardiographs
- Cardiovascular profiling systems
- Patient monitors



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