

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**OMRON Healthcare Europe B.V.**  
**Scorpius 33**  
**2132 LR 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  
(see attachment for products included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**



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

Effective Date: 2018-04-17  
Certificate Registration No.: SX 60128319 0001  
An audit was performed. Report No.: 21195011 009  
This Certificate is valid until: 2021-04-16

Certification Body



Date 2018-04-11



Dipl.-Ing. I. Munkler

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

**Attachment to  
Certificate**

**Registration No.:** SX 60128319 0001  
**Report No.:** 21195011 009

**Organization:** OMRON Healthcare Europe B.V.  
Scorpius 33  
2132 LR Hoofddorp  
Netherlands

**Scope:**

**Products included:**

- Electronic Sphygmomanometers and their accessories
- Nebulizers and their accessories
- Electronic and infrared thermometers and their accessories
- Peak flow meters
- Body fat analyzers
- Body composition analyzers
- Electroanalgesic Transcutaneous Stimulators and their accessories
- Electrocardiographs
- Nasal Aspirators

**Certification Body**



**Date:** 2018-04-17



**TÜVRheinland LGA Products GmbH**  
**TÜVRheinland**<sup>®</sup>  
Vertifizierungsstelle

**Dipl.-Ing. I. Munkler**