

# Certificate



## Quality Management System EN ISO 13485:2016

Registration No.: SX 1396541-1


Organization: Orbisana Healthcare GmbH  
Biberweg 24-26  
53842 Troisdorf  
Germany

Scope: - Design, development, production, storage, distribution and servicing of medical devices for the areas of tracheotomy/laryngectomy, enteral nutrition and incontinence.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

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