

# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1602324-1

Organization: GEMÜ GmbH  
Seetalstr. 210  
6032 Emmen  
Switzerland

Scope: Design and development, clean room manufacturing and distribution of plastic injection moulded medical technology products including clean room assembly of components for medical devices.

Sterile packaging and management of irradiation sterilization processes (X-Ray) for these products.

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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