

# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1448646-1

Organization: Santec Medicalprodukte GmbH  
Babenhäuser Str. 45  
63762 Großostheim  
Germany

Scope: Design and development, production and distribution of surgical suture materials, dynamic bubble traps and surgical accessories. Production of tubing systems

Products included:

- non absorbable surgical sutures
- implantable pledgets
- chordae loops
- tourniquet sets
- dynamic bubble traps
- polyester strings
- tube segments

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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