

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Santec Medicalprodukte GmbH
Babenhäuser Str. 45
63762 Großostheim
Deutschland

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

**Design and development, production and distribution of
surgical suture materials, dynamic bubble traps and
surgical accessories. Production of tubing systems.
(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: 2019-11-25
Certificate Registration No.: SX 60142615 0001
An audit was performed. Report No.: 21201075 025
This Certificate is valid until: 2022-09-26

Certification Body



Date 2019-11-25



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

**Attachment to
Certificate**

Registration No.: SX 60142615 0001
Report No.: 21201075 025

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

Scope:

Products included:

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

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02



Date: 2019-11-25


Dr. T. Kießling