

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60132454 0001

Report No.: 21201075 016

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

Products: Suture material and surgical accessories
(see attachment for products and sites included)
Replaces EC Certificate, Registration No.: HD 60088622 0001

Expiry Date: 2023-09-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-09-27

Date: 2018-09-20



Notified Body


Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60132454 0001
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Manufacturer: Santec Medicalprodukte GmbH
Babenhäuser Str. 45
63762 Großostheim
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Products included:

Surgical suture, non absorbable, sterile
- Polyester (Topester)
- Polypropylene (Toplene)

Surgical suture from metal, non absorbable, sterile
- Sternum wire, steel (Topsteel)
- Sternum wire, titanium (Topsteel)

Implant Chordae Loop, non absorbable, sterile

PTFE Pledgets, non absorbable, sterile

Dynamic Bubble Trap

Sterile surgical accessories
- polyester threads and tapes
- silicon strings (Toploop)
- Tourniquet-Sets



Notified Body



Dr. H. Lüdemann

Date: 2018-09-20

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60132454 0001
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For the following medical devices (class I, sterile)
the scope covers only the aspects of manufacture concerned
with securing and maintaining sterile conditions:

Products for wound care:
- ice syringes

Site included:
- Santec Medicalprodukte GmbH
Babenhäuser Str. 45
63762 Großostheim
Germany

Date: 2018-09-20



Notified Body


Dr. H. Lüdemann