

# QS Certificate

## (complete quality assurance system)

The LGA InterCert GmbH – notified body no. 1275 according to the EC Directive concerning medical devices – herewith confirms that the following company

**santec** *medicalprodukte gmbh*

**san**  
**tec**

**Mainstraße 32**  
**63868 Großwallstadt**  
**Germany**

applies a complete

### quality assurance system

for the scopes:

Tube Systems sterile, Infusion Device and –sets, Transfusion Systems and –sets,  
Dynamic Bubble Traps and non absorbable Surgical Suture

according to section 3 of the

### Directive 93/42/EEC, Annex II

for the design, manufacture and final inspection of the medical devices as specified in **the enclosure**.

The surveillance through the LGA InterCert GmbH is effected according to annex II, section 5.

This certificate is valid until August 28, 2013  
Registration no.: **1881857-006-000-001**

Audit report no.: 1891693  
of: September 14, 2009

Nuremberg, January 29, 2010<sup>(\*)</sup>

Roland Gruber  
Head of Certification Office  
Medical Devices



It is allowed for the company to sign the products specified in the enclosure with the adjoining sign.

**CE 1275**

(\*) first issue August 29, 2008, Reg. no.: 1881857-996-999 (Relocation of the company)

**Enclosure of the Certificate Registration no. 1881857-006-000 of the company  
 Santec Medicalprodukte GmbH, Mainstraße 32, 63868 Großwallstadt, Germany**

Date of expiry August 28, 2013

The above-mentioned certificate refers to following medical devices:

No.	Product	UMDNS- No.	Class
1.	<b>Tube systems, sterile</b> Infusion/Monitoring Line Organizer Systems 1.1 Lines a) High pressure PUR based, fabric reinforced with LLm/LLw b) High pressure PVC based LLw / rotation adapter (LLm) c) High pressure PVC based with LLm/LLw d) Syringe pump line PVC based e) Syringe pump line Coex based (PE/PVC) f) Micro lines PUR + Coex based  1.2 Drainage tubes, systems with bags  1.3 Irrigation tubes, systems incl. bags  1.4 Extensions a) Heidelberger extensions / connecting tubes  1.5 Connection a) Infusion links twofold, fourfold b) Infusion links MICRO PUR (threefold)  1.6 Manifolds	17-793	IIa
2.	<b>Infusion devices for the gravity, sterile</b> Intravenous Administration Sets, General-Purpose 2.1 Infusion set a) Contrast agent set  2.2 Connecting system for Buddles	16-649	IIa
3.	<b>Infusion devices for pumps, sterile</b> Pressure Infusors 3.1 Infusion device for pumps 3.2 Tube system for Tumeszens pump	13-100	

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 Santec Medicalprodukte GmbH, Mainstraße 32, 63868 Großwallstadt, Germany**

Date of expiry August 28, 2013

The above-mentioned certificate refers to following medical devices:

No.	Product	UMDNS-No.	Class
4.	<b>Transfusion systems and accessories, sterile</b> Blood Administration Sets 4.1 Several Transfusion sets 4.2 Blood heating tubes	10-421	Ila
5.	<b>Dynamic Bubble Trap, sterile</b> a) DBT	*	Ila
6.	<b>Surgical suture, non absorbable, sterile</b> a) Topline Polyester b) Topline Polypropylen	13-906 13-909	III
7.	<b>Surgical suture, sterile</b> a) Topline Stainless Steel	13-911	Ilb
8.	<b>Implant</b> a) Chordae Loop	*	III

\*At present no UMDNS number is available.

**Modification** (Relocation of the company) and **Supplement No. 8** of January 29, 2010  
 (Procedure-No.: 1891693; Registration No.: 1881857-006-000-001)

Nuremberg, January 29, 2010

Roland Gruber  
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