

# 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



## SERAG WIESSNER

**SERAG WIESSNER KG**

Zum Kugelfang 8-12

95119 Naila

Germany

**Division Surgical Sutures / Textile Implants**

applies a complete

**quality assurance system**

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 June 9, 2015

Registration no.: **1901801-006-001**

Nuremberg, June 10, 2010

Audit report no.: 1901801

of: April 30, 2010

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**

**Enclosure of the Certificate Registration no. 1901801-006-001 of the company  
 SERAG-WIESSNER KG, Zum Kugelfang 8-12, 95119 Naila, Germany**

Date of expiry June 9, 2015

Page 1 of 3

The above-mentioned certificate refers to the following medical devices:

No.	Product	UMDNS- No.	Class
1.	<b>Surgical suture made from polyester, non-absorbable</b> <ul style="list-style-type: none"> <li>▪ Seracor<sup>®</sup></li> <li>▪ Sulene<sup>®</sup></li> <li>▪ Terylene</li> <li>▪ Polyester Tape</li> </ul> Articles according to list CE04	13-906	III
2.	<b>Surgical suture made from polypropylene, non-absorbable</b> <ul style="list-style-type: none"> <li>▪ Serapren<sup>®</sup></li> </ul> Articles according to list CE05	13-909	III
3.	<b>Surgical suture made from polyvinylidene fluoride, non-absorbable</b> <ul style="list-style-type: none"> <li>▪ Seralene<sup>®</sup></li> </ul> Articles according to list CE12	15-255	III
4.	<b>Surgical suture made from PGA (polyglycolic acid), absorbable</b> <ul style="list-style-type: none"> <li>▪ Serafit<sup>®</sup></li> <li>▪ Serapid<sup>®</sup></li> </ul> Articles according to list CE02	13-908	III
5.	<b>Surgical suture made from PDO (polydioxanone), absorbable</b> <ul style="list-style-type: none"> <li>▪ Serasynth<sup>®</sup></li> </ul> Article according to list CE17	16-584	III
6.	<b>Surgical suture made from PGACL (polyglycolic acid-caprolactone), absorbable</b> <ul style="list-style-type: none"> <li>▪ Serafast<sup>®</sup></li> </ul> Articles according to list CE21	15-255	III
7.	<b>Surgical suture made from polyamide, non-absorbable</b> <ul style="list-style-type: none"> <li>▪ Seralon<sup>®</sup> incl. cassette</li> <li>▪ Supramid incl. cassette</li> <li>▪ Nylon</li> </ul> Articles according to list CE01	13-905	IIb
8.	<b>Surgical suture made from polyester, non-absorbable</b> <ul style="list-style-type: none"> <li>▪ Sulene<sup>®</sup> in the cassette</li> <li>▪ Terylene in the cassette</li> </ul> Articles according to list CE13	13-906	IIb

**Enclosure of the Certificate Registration no. 1901801-006-001 of the company  
 SERAG-WIESSNER KG, Zum Kugelfang 8-12, 95119 Naila, Germany**

Date of expiry June 9, 2015

Page 2 of 3

The above-mentioned certificate refers to the following medical devices:

No.	Product	UMDNS- No.	Class
9.	<b>Surgical suture made from silk, non-absorbable</b> ▪ Seraflex <sup>®</sup> incl. cassette Articles according to list CE06	13-910	IIb
10.	<b>Surgical suture made from steel wire, non-absorbable</b> ▪ Seranox <sup>®</sup> Articles according to list CE07	13-911	IIb
11.	<b>Surgical suture made from polyamide with titancoat, non-absorbable</b> ▪ Seratan <sup>®</sup> Articles according to list CE20	13-905	IIb
12.	<b>Laminar textile implants</b> ▪ Seramesh <sup>®</sup> ▪ Serasis <sup>®</sup> ▪ Seratom <sup>®</sup> ▪ Seragyn <sup>®</sup> ▪ Seratex <sup>®</sup> ▪ Seratim <sup>®</sup> Articles according to list CE09	12-510	IIb
13.	<b>Surgical Suture Accessories</b> ▪ Intracutaneous suture ▪ Tendon suture Articles according to list CE15	*	IIb
14.	<b>Bone wax</b> ▪ Bone wax Articles according to list CE14	10-459	IIb
15.	<b>Silicone Loops</b> ▪ Silicone Loops Articles according to list CE10	*	IIa

**Enclosure of the Certificate Registration no. 1901801-006-001 of the company  
SERAG-WIESSNER KG, Zum Kugelfang 8-12, 95119 Naila, Germany**

Date of expiry June 9, 2015

Page 3 of 3

The above-mentioned certificate refers to the following medical devices:

No.	Product	UMDNS- No.	Class
16.	<b>Instruments and Needles</b> <ul style="list-style-type: none"> <li>▪ Needles sterile</li> <li>▪ Safety Needles sterile</li> </ul> Articles according to list CE11	12-754	Is

\*At present no UMDNS number is available.

Nuremberg, June 10, 2010

Roland Gruber  
Head of Certification Office  
Medical Devices





**LGA**INTERCERT

## **Sertifikatas** **(išsami kokybės tikrinimo sistema)**

LGA InterCert GmbH – Nr. 1275, pagal Europos Sąjungos direktyvos medicinos prekėms šiuo patvirtina, kad kompanija

**SERAG WIESSNER KG**  
**Zum Kugelfang 8-12**  
**D-95119 Naila**

**Vokietija**

**Chirurginių siūlų padalinys/ Implantai**

Įgyvendino ir laikosi

**Kokybės priežiūros sistemos**  
Priskiriami

**DIREKTYVA 93/42/EEC, PRIEDAS II**

Dėl projektavimo, gamybos ir aptarnavimo medicinos prietaisų patikslinta priede.

Priežiūra LGA InterCert GmbH priskirta annex II, dalis 5

Sertifikatas galioja iki 2015 06 09  
Registracijos Nr. 1901801-006-001

Audito Nr. 1901801  
Data: 2010 04 30

Niurnbergas, 2010.06.10

/parašas/

Roland Gruber  
Sertifikavimo ofisas  
Medicinos prietaisai



Priedas prie Kokybės Priežiūros sistemos sertifikato Nr. 1901801-006-001. Kompanijos  
SERAG- WIESSNER KG, Zum Kugelfang 8-12, 95119 Naila, Vokietija

Galioja iki 2015-06-09

Psl. 1 iš 3

Priskirtos sekančios medicinos priemonės

<u>Nr.</u>	<u>Produktas</u>	<u>UMDNS Nr.</u>	<u>Klasė</u>
<b>1. Chirurginiai siūlai iš poliesterio</b>		<b>13-906</b>	<b>III</b>
	▪ Seracor <sup>®</sup>		
	▪ Sulene <sup>®</sup>		
	▪ Terylene <sup>®</sup>		
	▪ Poliesterio kasetė		
<b>2. Chirurginiai siūlai iš polipropileno</b>		<b>13-909</b>	<b>III</b>
	▪ Serapren <sup>®</sup>		
<b>3. Chirurginiai siūlai polivinilinio fluorida</b>		<b>13-905</b>	<b>IIb</b>
	▪ Seralene <sup>®</sup>		
<b>4. Chirurginiai siūlai iš poliglikolio rūgšties</b>		<b>13-908</b>	<b>III</b>
	▪ Serafit <sup>®</sup>		
	▪ Serapid <sup>®</sup>		
<b>5. Chirurginiai siūlai iš polidioksanono</b>		<b>16-584</b>	<b>III</b>
	▪ Serasynt <sup>®</sup>		
<b>6. Chirurginiai siūlai iš poliglikolio rūgšties-kaprolaktono</b>		<b>15-255</b>	<b>III</b>
	▪ Serafast <sup>®</sup>		
<b>7. Chirurginiai siūlai iš poliamido</b>		<b>13-905</b>	<b>IIb</b>
	▪ Seralon <sup>®</sup> įsk. kasetes		
	▪ Supramid <sup>®</sup> įsk. kasetes		
	▪ Nylon		
<b>8. Chirurginiai siūlai iš poliesterio, kasetėse</b>		<b>13-906</b>	<b>IIb</b>
	▪ Sulene <sup>®</sup>		
	▪ Terylene <sup>®</sup>		

**Priedas prie Kokybės Priežiūros sistemos sertifikato Nr. 1901801-006-001. Kompanijos  
SERAG- WIESSNER KG, Zum Kugelfang 8-12, 95119 Naila, Vokietija**

Galioja iki 2015-06-09

Psl. 2 iš 3

Priskirtos sekančios medicinos priemonės

<u>Nr.</u>	<u>Produktas</u>	<u>UMDNS Nr.</u>	<u>Klasė</u>
<b>9.</b>	<b>Chirurginiai siūlai iš polivinilideno fluorido</b> <ul style="list-style-type: none"><li>▪ Seraflex<sup>®</sup> jsk. kasetes</li></ul>	<b>13-910</b>	<b>III</b>
<b>10.</b>	<b>Chirurginiai siūlai iš poliesterio, kasetėse</b> <ul style="list-style-type: none"><li>▪ Seranox<sup>®</sup></li></ul>	<b>13-911</b>	<b>IIb</b>
<b>11.</b>	<b>Chirurginiai siūlai iš polipropileno su titanu</b> <ul style="list-style-type: none"><li>▪ Seratan<sup>®</sup></li></ul>	<b>13-905</b>	<b>IIb</b>
<b>12.</b>	<b>Tekstilės implantai</b> <ul style="list-style-type: none"><li>▪ Seramesh<sup>®</sup></li><li>▪ Serasis<sup>®</sup></li><li>▪ Seratom<sup>®</sup></li><li>▪ Seragyn<sup>®</sup></li><li>▪ Seratex<sup>®</sup></li><li>▪ Seratim<sup>®</sup></li></ul>	<b>12-510</b>	<b>IIb</b>
<b>13.</b>	<b>Chirurginių siūlų priedai</b> <ul style="list-style-type: none"><li>▪ Poodinių sluoksnių siūlai</li><li>▪ Sausgyslių siūlai</li></ul>	<b>*</b>	<b>IIb</b>
<b>14.</b>	<b>Kaulų vaškas</b>	<b>10-459</b>	<b>IIb</b>
<b>15.</b>	<b>Silikoninės kilpos</b> <ul style="list-style-type: none"><li>▪ Silikoninės kilpos</li></ul>	<b>*</b>	<b>IIa</b>

**Priedas prie Kokybės Priežiūros sistemos sertifikato Nr. 1901801-006-001. Kompanijos  
SERAG- WIESSNER KG, Zum Kugelfang 8-12, 95119 Naila, Vokietija**

Galioja iki 2015-06-09

Psl. 3 iš 3

Priskirtos sekančios medicinos priemonės

<u>Nr.</u>	<u>Produktas</u>	<u>UMDNS Nr.</u>	<u>Klasė</u>
<b>16.</b>	<b>Instrumentai ir adatos</b>	<b>12-754</b>	<b>Is</b>
	<ul style="list-style-type: none"><li>▪ Sterilios adatos</li><li>▪ Sterilios saugumo adatos</li></ul>		

\* Šiuo metu UMDNS numeris nėra žinomas

Nurembergas, 2010-06-10

/PARAŠAS/  
Roland Gruber  
Medicinos prietaisų  
Sertifikavimo ofisas