



## EC CERTIFICATE

**According to Annex II of the Directive 93/42/EEC on Medical Devices**

### Full Quality Assurance System

**Certificate Number: 2195-MED-1335101**

**Manufacturer:** Pine Sutures Co., LTD.  
206 Techno 2-ro Yuseong-gu Daejeon 305-500 Korea

**Product Category(ies):** Sterile Absorbable Sutures with Needle

**Type(s)/Model(s):**  
(1) Polyglycolide-Co-L-Lactide (PGLA)  
(2) Polyglycolide-Co-L-Lactide (PGLA) Quick  
(3) Polyglycolicacid (PGA)  
(4) Polyglycolicacid (PGA) Quick  
(5) Poly(p-dioxanone)  
(6) Polyglycolide-co-caprolactone

**Brand Name :**  
(1) GLSORB, (2) GLSORB-Quick  
(3) PGSORB, (4) PGSORB-Quick  
(5) DOSORB, (6) GCSORB

**Final Report No:** 2195-MED-1311013

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II, Section 3 and Section 4 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining sterile conditions of the respective product category(ies) and accessories and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC.

Szutest must be informed of any significant changes in the design and/or construction of the product category(ies).

***This EC certificate is valid till 2018.12.16***

Istanbul, 2013.12. 17



Mehmet IŞIKLAR  
General Manager







**SZUTEST**  
NOTIFIED BODY 2195

## EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Article 4 of the Directive 93/42/EEC on Medical Devices

### Full Quality Assurance System

**Certificate Number: 2195-MED-1335101-D01**

**Manufacturer:**

**Pine Sutures Co., LTD.**

*206 Techno 2-ro Yuseong-gu Daejeon 305-500 Korea*

**Product Category(ies):**

**Sterile Absorbable Surgical Sutures with Needle**

**Type(s)/Model(s):**

(1) Polyglycolide-Co-L-Lactide (PGLA)  
(2) Polyglycolide-Co-L-Lactide (PGLA) Quick

**Brand Name :**

(1) GLSORB, (2) GLSORB-Quick

**Final Report No:**

2195-MED-1311013

Published by Szutest, Notified Body 2195, The EC design examination certificate refers to the mentioned product. It certifies that the design documentation of the product complies with Annex II, Article 4 of the directive. The manufacturer is subject to EC surveillance in accordance with Annex II, Article 5 of 93/42/EEC Medical Devices Directive.

***This EC Design Examination Certificate is valid till 2018.12.16***

Istanbul, 2013.12.17



Mehmet IŞIKLAR  
General Manager







**SZUTEST**  
NOTIFIED BODY 2195

# EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Article 4 of the Directive 93/42/EEC on Medical Devices

## Full Quality Assurance System

**Certificate Number: 2195-MED-1335101-D02**

**Manufacturer:** Pine Sutures Co., LTD.  
206 Techno 2-ro Yuseong-gu Daejeon 305-500 Korea

**Product Category(ies):** Sterile Absorbable Surgical Sutures with Needle

**Type(s)/Model(s):** (1) Polyglycolicacid (PGA)  
(2) Polyglycolicacid (PGA) Quick

**Brand Name :** (1) PGSORB, (2) PGSORB-Quick

**Final Report No:** 2195-MED-1311013

Published by Szutest, Notified Body 2195, The EC design examination certificate refers to the mentioned product. It certifies that the design documentation of the product complies with Annex II, Article 4 of the directive. The manufacturer is subject to EC surveillance in accordance with Annex II, Article 5 of 93/42/EEC Medical Devices Directive.

***This EC Design Examination Certificate is valid till 2018.12.16***

Istanbul, 2013.12.17



Mehmet IŞIKLAR  
General Manager







**SZUTEST**  
NOTIFIED BODY 2195

## EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Article 4 of the Directive 93/42/EEC on Medical Devices

### Full Quality Assurance System

**Certificate Number: 2195-MED-1335101-D03**

**Manufacturer:** Pine Sutures Co., LTD.

206 Techno 2-ro Yuseong-gu Daejeon 305-500 Korea

**Product Category(ies):** Sterile Absorbable Surgical Sutures with Needle

**Type(s)/Model(s):** (1) Poly(p-dioxanone)

**Brand Name :** (1) DOSORB

**Final Report No:** 2195-MED-1311013

Published by Szutest, Notified Body 2195, The EC design examination certificate refers to the mentioned product. It certifies that the design documentation of the product complies with Annex II, Article 4 of the directive. The manufacturer is subject to EC surveillance in accordance with Annex II, Article 5 of 93/42/EEC Medical Devices Directive.

***This EC Design Examination Certificate is valid till 2018.12.16***

Istanbul, 2013.12.17



Mehmet IŞIKLAR  
General Manager





**SZUTEST**  
NOTIFIED BODY 2195

## EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Article 4 of the Directive 93/42/EEC on Medical Devices

### Full Quality Assurance System

**Certificate Number: 2195-MED-1335101-D04**

**Manufacturer:** Pine Sutures Co., LTD.

206 Techno 2-ro Yuseong-gu Daejeon 305-500 Korea

**Product Category(ies):** Sterile Absorbable Surgical Sutures with Needle

**Type(s)/Model(s):** (1) Polyglycolide-co-caprolactone

**Brand Name :** (1) GCSORB

**Final Report No:** 2195-MED-1311013

Published by Szutest, Notified Body 2195, The EC design examination certificate refers to the mentioned product. It certifies that the design documentation of the product complies with Annex II, Article 4 of the directive. The manufacturer is subject to EC surveillance in accordance with Annex II, Article 5 of 93/42/EEC Medical Devices Directive.

***This EC Design Examination Certificate is valid till 2018.12.16***

Istanbul, 2013.12.17



Mehmet IŞIKLAR  
General Manager

