

# 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):	<ol> <li>Polyglycolide-Co-L-Lactide (PGLA)</li> <li>Polyglycolide-Co-L-Lactide (PGLA) Quick</li> <li>Polyglycolicacid (PGA)</li> <li>Polyglycolicacid (PGA) Quick</li> <li>Polyglycolicacid (PGA) Quick</li> <li>Poly(p-dioxanone)</li> <li>Polyglycolide-co-caprolactone</li> </ol>
Brand Name :	<ul> <li>(1) GLSORB, (2) GLSORB-Quick</li> <li>(3) PGSORB, (4) PGSORB-Quick</li> <li>(5) DOSORB, (6) GCSORB</li> </ul>
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).



SZUTEST Teknik Kontrol va Belgalendirme Hizhetlen Tic. Ltd.: Sri. SZUTEST Plaza, Nato Yole Cd. Çam Sk. No:7 Ümraniye, ISTANBUL, TÜRKİYE



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



Mehmet IŞIKLAR General Manager

İstanbul, 2013.12.17

This version of certificate has come into force on 2013.11.06

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SZUTEST Teknik Kontrol ve Belgelendirme Hizmetlen Tic. Ltd. Şti. SZUTEST Plaza, Nato Yolu Cd. Çam Sk. No.7 Ümraniye, İSTANBÜL, TÜRKİYE



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

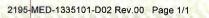
Published by Szutest, Notified Body 2195, The EC design examination certificate refers to the mentioned product. It certifies that the design documentation of the product complies with Annex II, Article 4 of the directive. The manufacturer is subject to EC surveillance in accordance with Annex II, Article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

This EC Design Examination Certificate is valid till 2018.12.16



Mehmet IŞIKLAR General Manager

This version of certificate has come into force on 2013.11.06





SZUTEST Teknik Kontrol ve Belgelendirme Hizmetien Tic. Ltd. Sti. SZUTEST Plaza, Nato Yolu Cd. Çam Sk. No:7 Ümraniye, İSTANBUL, TÜRKİYE

İstanbul, 2013.12.17



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



Mehmet IŞIKLAR General Manager

Istanbul, 2013.12.17

This version of certificate has come into force on 2013,11.06

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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.
Product Category(ies):	206 Techno 2-ro Yuseong-gu Daejeon 305-500 Korea 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



Mehmet IŞIKLAR General Manager

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İstanbul, 2013.12.17

This version of certificate has come into force on 2013.11.06

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