

EC DESIGN EXAMINATION CERTIFICATE

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

Certificate Number: 2195-MED-381435801-D01

Manufacturer: LOTUS SURGICALS Pvt. Ltd.
Khasra No. 1051 / 1&2, Twin Industrial Estate, Selaqui, Dehradun – 248197,
Uttarakhand, INDIA

Product(s): Sterile Absorbable and Non Absorbable Surgical Sutures

Model(s): Product specifications are stated on the second page.

Reference Report No: MM0327-P004-R01, MM0327-P004-R02

Issued by Szutest, Notified Body 2195, this document certifies that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive.

The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

This EC Design Examination certificate is valid till 2024-05-26.

Issue Date: 2015-02-13
Revision No.: 03 Recertification
Revision Date: 2019-06-20



Rukiye BALKAN
Deputy General Manager

SZUTEST

Certificate Number: 2195-MED-381435801-D01

Product Specifications

Product Categories	Type (Models)	Generic Name
Sterile Absorbable Surgical Sutures	Solus ®	Braided Coated Polyglycolic Acid
	Solus Swift ®	Braided Coated Short Term Polyglycolic Acid
	Solus 910 ®	Braided Coated Poly (Glycolide-Co-L-Lactide) / Polyglactin - 910
	Solus Swift 910 ®	Braided Coated Short Term Poly (Glycolide-Co-L-Lactide) / Polyglactin - 910
	Monolus ®	Monofilament Poly (Glycolide Co-Caprolactone)
	Mass ®	Monofilament Poly (p-dioxanone)
	Barb-E ®	Monofilament Poly (p-dioxanone)
Sterile Non Absorbable Surgical Sutures	Esterlus ®	Braided Coated Polyester
	Silkus ®	Braided Coated Silk
	Prolus ®	Monofilament Polypropylene
	Nylus ®	Monofilament Polyamide



SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

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EC DESIGN EXAMINATION CERTIFICATE

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

Certificate Number: 2195-MED-381435801-D02

Manufacturer: LOTUS SURGICALS Pvt. Ltd.
Khasra No. 1051 / 1&2, Twin Industrial Estate, Selaqui, Dehradun – 248197,
Uttarakhand, INDIA

Product(s): Partially Absorbable Surgical Mesh

Model(s): Pro- AB® Poly(Glycolide Co-Caprolactone) and Polypropylene Mesh

Reference Report No: MM0327-P004-R01, MM0327-P004-R02

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Issue Date: 2015-02-13
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Revision Date: 2019-06-20



Rukiye BALKAN
Deputy General Manager