

EC CERTIFICATE

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

Full Quality Assurance System

Certificate Number: 2195-MED-381435801

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

Product(s): (1) Sterile Non Absorbable Monofilament Stainless Steel Surgical Sutures
(2) Sterile Non Absorbable Mesh
(3) Sterile Absorbable and Non Absorbable Surgical Sutures
(4) Sterile Partially Absorbable Surgical Mesh

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

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

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) 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 and unannounced audits.

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

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

Issue Date: 2014-12-24
Revision No.: 03 Recertification
Revision Date: 2019-06-20



A handwritten signature in blue ink, appearing to read 'Rukiye BALKAN', is positioned above the printed name.

Rukiye BALKAN
Deputy General Manager

SZUTEST

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Product Specifications

Product Categories	Type (Models)	Generic Name
Sterile Non- Absorbable Monofilament Stainless Steel Surgical Sutures	Stelus ®	Monofilament stainless steel 316 L
Sterile Non Absorbable Surgical Mesh	Prolus ® Mesh	Polypropylene Mesh
	Prolus ® Lite Mesh	Polypropylene Mesh
	Prolus ® Ultra Lite Mesh	Polypropylene Mesh
	Pro-Visc ®	Polyester and Polyurethane Composite Mesh
	Pro-Visc ® 3D	Polyester and Polyurethane Composite Mesh
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
Sterile Partially Absorbable Surgical Mesh	Pro- AB ®	Poly (Glycolide Co-Caprolactone) and Polypropylene Mesh

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE

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