



## 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) Non Absorbable Monofilament Stainless Steel Surgical Sutures  
(2) Non Absorbable Mesh  
(3) Absorbable and Non Absorbable Surgical Sutures  
(4) Partially Absorbable Surgical Mesh

**Model(s):** (See 2<sup>nd</sup> page for system configurations)

**Final Report No:** 2195-MED-1412006, 2195-MED-1502007

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II, 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 and sterile 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 2019-12-23*

Istanbul, 2014-12-24  
Rev.01, 2015-02-13



Özgür Vicdan  
Deputy General Manager





**Product Specifications**

Product Categories	Type (Models)	Generic Name
<b>Non- Absorbable Monofilament Stainless Steel Surgical Sutures</b>	Stelus ®	Monofilament stainless steel 316 L
<b>Non Absorbable Surgical Mesh</b>	Prolus ® Mesh	Polypropylene Mesh
	Prolus ® Lite Mesh	Polypropylene Mesh
	Prolus ® Ultra Lite Mesh	Polypropylene Mesh
	Freedom ®	Polypropylene Mesh
	Pro-Visc ®	Polyester and Polyurethane Composite Mesh
	Pro-Visc® 3D	Polyester and Polyurethane Composite Mesh
<b>Absorbable Surgical Sutures</b>	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)
<b>Non Absorbable Surgical Sutures</b>	Esterlus ®	Braided Coated Polyester
	Silkus ®	Braided Coated Silk
	Prolus ®	Monofilament Polypropylene
	Nylus ®	Monofilament Polyamide
<b>Partially Absorbable Surgical Mesh</b>	Pro- AB®	Poly(Glycolide Co-Caprolactone) and Polypropylene Mesh

This version of certificate has come into force on 2013.11.06. Page 2/2 2195-MED- 381435801 REV.01

