

## 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).

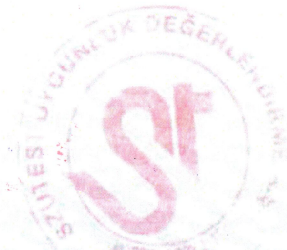
*Ramesh Chandra Tiwari*  
20/11/2020

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

**RAMESH CHANDRA TIWARI**  
ADVOCATE & NOTARY  
GOVT. OF INDIA

Res. 129, A-Wing, Appli Ekta Hsg. Soc  
Nav Pada, Marol Naka, A. K. Road,  
Andheri (E), Mumbai-400 059.

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



*Rukiye Balkan*

Rukiye BALKAN  
Deputy General Manager

A copy of this document / CERTIFICATE  
has been recorded with the Chamber



*Sadhana Rajesh Desai*  
MS. SADHANA RAJESH DESAI  
MANAGER

Authorised Signatory

Bombay Chamber of Commerce and Industry

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. No. 13.2602... Date

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

JAN 2020

This version of certificate has come into force on 23.03.2017. 2195-MED-381435801-Rev.03



**CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ  
CONSULAR AUTHENTICATION**

1. Quốc gia  
**Country** VIỆT NAM  
Giấy tờ, tài liệu này  
*This public document*  
2. do Ông (Bà)  
**has been signed by** SUNIL CHANAP ky  
3. với chức danh  
**acting in the capacity of** Cán bộ Lãnh sự  
4. và con dấu của  
**bears the seal/stamp of** Bộ Ngoại giao Ấn Độ  
được chứng nhận / hợp pháp hóa lãnh sự  
**Certified** Niu Đê-li ngày 03/02/2020  
5. tại Đại sứ quán Việt Nam tại Ấn Độ  
7. cơ quan cấp  
**by** 0074.7/20-HPH  
8. Số  
**Nº**

Ký tên và đóng dấu  
**TL DA/Signature of the Notary**  
Bi thư thứ hai / Second Secretary



10125

सं० दिनांक  
No. Date  
वाणिज्य मंडल में सहायक सचिव उप सचिव/सचिव के  
हस्ताक्षर सत्यापित किए गये हैं।  
The Signature of **Asst. Secretary/Dy. Secretary/Secretary of Chamber of Commerce** Attested.  
विक्रम मंत्रालय इन दस्तावेज के किसी भी विषय वस्तु  
की जिम्मेदारी नहीं लेता।  
Ministry of External Affairs accepts  
no responsibility for the contents of this  
document.

17 JAN 2020



(सुनील चनाप)  
**(SUNIL CHANAP)**  
अनुभाग अधिकारी (ओ.आई.)  
Section Officer (OI)  
सी. पी. सी. प्रभाग / C.P.V. Division  
विदेश मंत्रालय, नई दिल्ली  
Ministry of External Affairs, New Delhi