



# CERTIFICATE

*This certifies that the Quality management system for medical devices of company*

## Unisur Lifecare Private Limited

No. 15/1, 2, 3, Andrahalli Main Road, Acharya Industrial Complex,  
Vishwaneedam Post, 560 091 Bangalore, Karnataka, India



*has been assessed by 3EC International  
and found to be in conformance with the following standard:*

## EN ISO 13485:2016

*for the following scope:*

**DESIGN, DEVELOPMENT, MANUFACTURE AND SUPPLY OF DEVICES  
FOR WOUND CARE: SURGICAL SUTURES, SURGICAL MESH AND BONE WAX**

Certificate No.: M-0387/19

Date of issuance: October 31st, 2019

Original date of approval: November 1st, 2016

This certificate is valid from **October 31st, 2019** to **October 30th, 2022** on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

*Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic*



Dr. Katarina Tomin Srdošová  
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices.



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

# EC CERTIFICATE

## No. 2019-MDD/QS-073

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll. certifies that the medical device of Class IIb,

### **Sterile Non-absorbable Surgical Suture**

(for detailed list refer to Annex)

manufactured by company

### **Unisur Lifecare Private Limited**

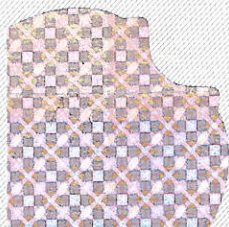
No. 15/1, 2, 3, Andrahalli Main Road, Acharya Industrial Complex,  
Vishwaneedam Post, 560 091 Bangalore, Karnataka, India

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended by 2007/47/EC.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended by 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. SK-0500-19, and the Final protocol No. 310278/2019.

*This certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26<sup>th</sup>, 2024 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.



  
Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

In Bratislava, on November 14<sup>th</sup>, 2019



# ANNEX TO EC CERTIFICATE No. 2019-MDD/QS-073

issued for the company

**Unisur Lifecare Private Limited**  
No. 15/1, 2, 3, Andrahalli Main Road, Acharya Industrial Complex,  
Vishwaneedam Post, 560 091 Bangalore, Karnataka, India

## List of medical devices covered by the EC Certificate:

### Product name: Non-absorbable Surgical Suture

| Generic Name                                       | Brand Name (s)   | USP Size   |
|--|--|--|
| Black Braided Silk                                 | UNISIL, ADVAMED-SILK, MARFLOW-SILK, UNISIL FAST, M-SILK, ALPHA-SILK, I SILK, N-CARE SILK, RHIZOSILK              | 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3 |
| Monofilament Stainless Steel<br>LVM 316 Grade wire | MONOSTEEL, ADVAMED-STEEL, MARFLOW-STEEL, MONOSTEEL FAST, M-STEEL, ALPHA-STEEL, I STEEL, N-CARE STEEL, RHIZOSTEEL | 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5, 6, 7          |

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Dr. Katarina Tomin Srdošová  
Responsible to act on behalf of NB 2265

In Bratislava, on November 14<sup>th</sup>, 2019  
Valid until May 26<sup>th</sup>, 2024