



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**

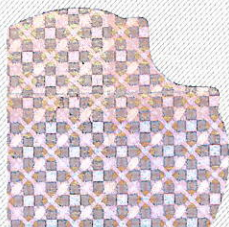
No. 15/1, 2, 3, Andrahalli Main Road, Acharya Industrial Complex,  
Vishwaneedam Post, 560 091 Bangalore, Karnataka, India

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 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