



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

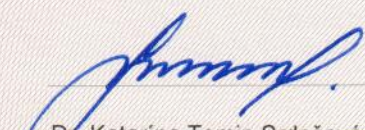
is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended by 2007/47/EC.

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 26th, 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. Katarina Tomin Srdošová
Responsible to act on behalf of NB 2265

In Bratislava, on November 14th, 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

Black Braided Silk

Brand Name (s)

UNISIL, ADVAMED-SILK,
MARFLOW-SILK, UNISIL
FAST, M-SILK, ALPHA-
SILK, I SILK, N-CARE
SILK, RHIZOSILK

USP Size

10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0,
0, 1, 2, 3

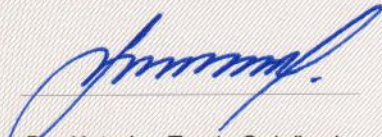
Monofilament Stainless Steel
LVM 316 Grade wire

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

In Bratislava, on November 14th, 2019
Valid until May 26th, 2024

EC DECLARATION OF CONFORMITY

With regard to MDD 93/42/EEC as amended by 2007/47/EC for medical devices

Name of the Company : **UNISUR LIFECARE PRIVATE LIMITED**
 Product : **STERILE NON-ABSORBABLE SURGICAL SUTURES**
 Classification and Justification : Refer Page 2 of 3
 Model/Type ref. : Refer Page 2 to 3
 Address : No. 15/1, 2, 3 Andrahalli Main Road, Acharya Industrial Complex, Vishwaneedam Post, Karnataka, Bangalore - 560091, India.

We, hereby under our sole responsibility declare that the product to which this declaration relates, is in conformity with the relevant provisions of standards and other normative document(s) and full fills the essential requirements of 93/42/EEC. We have presented our product and our system to 3EC International a.s, (Notified Body Number 2265) addressed at Hraničná 18, 82105 Bratislava, for conformity assessment as per Annex II excluding section IV of MDD 93/42/EEC as amended by 2007/47/EC.

This declaration is based on

- a) EN ISO 15223-1:2016, EN ISO 20417:2021, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 10993-1:2020, EN ISO 11135:2014, EN ISO 11138-2:2017
- b) Non-harmonized Standards: ISO/TR 20416:2020
- c) Technical File. (USPL-TCF-MD-04)

AUTHORIZED REPRESENTATIVE
 MEDDEVICES LIFE SCIENCE B.V.
 Kraijenhoffstraat 137 A,
 1018RG Amsterdam, Netherlands.
 Ph. No.: +31202254558
 e-mail ID: nk@meddevices.net

CE CERTIFICATE NUMBER	DATE OF ISSUE	CERTIFICATE VALIDITY
2019-MDD/QS-073	November 14 th , 2019	May 26 th , 2024

Manufacturer : **UNISUR LIFECARE PRIVATE LIMITED**

Name : Mr. Pavan D.C (Managing Director)

Signature :

Date : October 18th, 2021

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Registered Office
 Bangalore

No. 15/1,2,3, Andrahalli Main Road, Acharya Indl. Complex
 Vishwaneedam Post, Near Anupama School
 Bangalore - 560 091 Karnataka, INDIA
 Tele: +91 9108 990 400
 E-mail: info@universalsutures.com
 CIN: U33110KA2015PTC078111

Corporate Office
 Bangalore

Unit No. 303, 3rd floor, Brigade Rubix,
 Plot No: MYS357 in Peenya Plantation, HMT Factory Main Road,
 Bangalore - 560 013, Karnataka, INDIA
 Tele: +91 80 4166 6920
 E-mail: care@universalsutures.com
 www.universalsutures.com

LIST OF MEDICAL DEVICES COVERED IN THE DECLARATION**Classification and Justification:**

As per annexure IX of MDD 93/42/EEC as amended by 2007/47/EC, section 2.4 Rule 8 it's a Class IIb Medical Device.

[All implantable devices and long-term surgically invasive devices are in Class IIb]

Generic Name: BLACK BRAIDED SILK			
Brand Name: UNISIL, ADVAMED-SILK, MARFLOW-SILK, UNISIL FAST, M-SILK, ALPHA-SILK, I SILK, N-CARE SILK, RHIZOSILK			
GMDN Code: 13910			
USP Size Min.	Metric size (Gauge No.) Max.	Needle Profile	Needle curvature
3	6	Taper point (Round body), Taper cut, Cutting, Reverse cutting, Blunt, Spatulated, Trocarn point, Diamond point	1/2 Circle 1/4 Circle 3/8 Circle 5/8 Circle Straight
2	5		
1	4		
0	3.5		
2-0	3		
3-0	2		
4-0	1.5		
5-0	1		
6-0	0.7		
7-0	0.5		
8-0	0.4		
9-0	0.3		
10-0	0.2		

Registered Office

Bangalore

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