



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

## EC CERTIFICATE

No. 2020-MDD/QS-135

issued in compliance with the Council Directive 93/42/EEC as amended,  
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

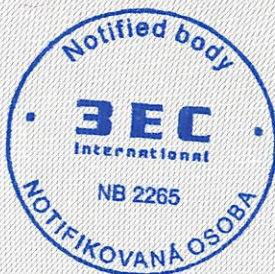
No. 15/1, 2, 3, Andrahalli Main Road, Acharya Industrial Complex,  
Vishwaneedam Post, 560 091 Bangalore, Karnataka, India

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

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. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT\_78 and the Final protocol No. 310506/2020.

*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 such is required. 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. Katarina Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on December 27<sup>th</sup>, 2020  
This certificate supersedes the EC Certificate No. 2016-MDD/QS-030/A issued on November 14<sup>th</sup>, 2019





## ANNEX TO EC CERTIFICATE No. 2020-MDD/QS-135

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: Sterile Non-absorbable Surgical Suture

Generic Name	Brand Name (s)	USP Size
Polyamide Suture	UNILON, UNILON FAST, ADVAMED-NYLON, M-LON, i Lon, N-CARE Nylon, RHIZOLON, MDB-LON, GPCLOX	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5
Polypropylene Suture	UNILENE, UNILENE FAST, ADVAMED-POLYPROPYLENE, M-LENE, i Lene, N-CARE Polypropylene, RHIZOLENE, MDB-LENE, GPCLENE	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5
Polyester Suture	UNIBOND, UNIBOND FAST, ADVAMED-POLYESTER, M-BOND, i Bond, N-CARE Polyester, RHIZOBOND, MDB-BOND, GPCBOND	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5

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

At Bratislava, on December 27<sup>th</sup>, 2020  
Valid until May 26<sup>th</sup>, 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) Harmonized Standards: 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-02)

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
2020-MDD/QS-135	December 27 <sup>th</sup> , 2020	May 26 <sup>th</sup> , 2024

Manufacturer : **UNISUR LIFECARE PRIVATE LIMITED**

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

Signature : 

Date : October 18<sup>th</sup>, 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: BRAIDED AND COATED POLYESTER SUTURE			
Brand Name – UNIBOND, UNIBOND FAST, ADVAMED–POLYESTER, M–BOND, i Bond, N–CARE Polyester, RHIZOBOND, MDB-BOND, GPCBOND			
GMDN Code: 13906			
USP Size Min.	Metric size (Gauge No.) Max.	Needle Profile	Needle curvature
5	7	TAPER POINT (ROUND BODY), TAPER CUT, CUTTING, REVERSE CUTTING, BLUNT, SPATULATED, TROCAR POINT, DIAMOND POINT	½ CIRCLE ¼ CIRCLE 3/8CIRCLE 5/8 CIRCLE STRAIGHT
4	6		
3	6		
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		

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<b>Generic Name: MONOFILAMENT POLYPROPYLENE SUTURE</b>			
<b>Brand Name – UNILENE, UNILENE FAST, ADVAMED–POLYPROPYLENE, M–LENE, i Lene, N–CARE Polypropylene, RHIZOLENE, MDB-LENE, GPCLENE</b>			
<b>GMDN Code: 13909</b>			
USP Size Min.	Metric size (Gauge No.) Max.	Needle Profile	Needle curvature
5	7	TAPER POINT (ROUND BODY), TAPER CUT, CUTTING, REVERSE CUTTING, BLUNT, SPATULATED, TROCER POINT, DIAMOND POINT	½ CIRCLE ¼ CIRCLE 3/8CIRCLE 5/8 CIRCLE STRAIGHT
4	6		
3	6		
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		

<b>Generic Name: MONOFILAMENT POLYAMIDE SUTURE</b>			
<b>Brand Name –UNILON, UNILON FAST, ADVAMED–NYLON, M–LON, i Lon, N–CARE Nylon, RHIZOLON, MDB-LON, GPCLON</b>			
<b>GMDN Code :38000</b>			
USP Size Min.	Metric size (Gauge No.) Max.	Needle Profile	Needle curvature
5	7	TAPER POINT (ROUND BODY), TAPER CUT, CUTTING, REVERSE CUTTING, BLUNT, SPATULATED, TROCER POINT, DIAMOND POINT	½ CIRCLE ¼ CIRCLE 3/8CIRCLE 5/8 CIRCLE STRAIGHT
4	6		
3	6		
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		

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