

Agenția Medicamentului  
și Dispozitivelor Medicale

## NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale

nr. 63 din 02.10.2023

Solicitantul **FPC "SOGNO" S.R.L.**, cu sediul MD-2028, mun. Chișinău, str. Academiei, 2, tel.: (022) 72-75-25/  
**069501992**, fax: (022) 73-83-42, e-mail: sognomd@gmail.com,  
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive  
medicale pentru introducerea și punerea la dispoziție pe piață a:

**Conform Anexei nr.3 "Lista dispozitivelor medicale UNISUR Lifecare (Sutură non-  
absorbabilă)"**

**Se anexează următoarele acte:**

1. Certificate CE\_Full Quality\_Design-Examination.
2. Declarație de Conformitate.
3. Scrisoarea autorizată a producătorului.
4. Declarație pe propria răspundere.
5. Lista dispozitivelor medicale.

Data: 02.10.2023



### Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	Accept
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	No. 7600 din 02.10.2023
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Clara Techi Doinița
Semnătura persoanei responsabile	CTD

**Către Agenția Medicamentului și Dispozitive Medicale**

## **DECLARAȚIE PE PROPRIE RĂSPUNDERE**

Solicitant: **FPC "SOGNO" SRL**, cu sediul m.Chișinău, str. Academiei nr.2, Republica Moldova,  
declar pe proprie răspundere, cunoscând prevederile art. **352<sup>1</sup>**, Codul Penal al Republicii Moldova cu privire la  
falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale:

**Conform Anexei nr.3 "Lista dispozitivelor medicale UNISUR Lifecare (Sutură non-absorbabilă)"**

Sunt autentice și corespund realității.

Iarovoi Petru, Director



Semnătura

Data: 02.10.2023

**Lista dispozitivelor medicale UNISUR Lifecare (Sutură non-absorbabilă)**

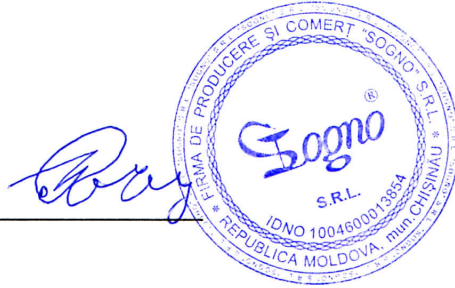
Nr d/o	Numărul de catalog	Denumire	Denumirea comercială	Model	Tip dispozitiv	GMDN Code
1	5B75DZ35	Mătasă neagră împletită USP 2	Unisil	75cm, 1/2 cerc taper point 35mm	Dispozitiv chirurgical invaziv	13910
2	5C75DZ35	Mătasă neagră împletită USP 1	Unisil	75cm, 1/2 cerc taper point 35mm	Dispozitiv chirurgical invaziv	13910
3	5D75DK25	Mătasă neagră împletită USP 0	Unisil	75cm, 1/2 cerc taper cutting 25mm	Dispozitiv chirurgical invaziv	13910
4	5D75CK30	Mătasă neagră împletită USP 0	Unisil	75cm, 3/8 cerc taper cutting 30mm	Dispozitiv chirurgical invaziv	13910
5	5E75DK25	Mătasă neagră împletită USP 2/0	Unisil	75cm, 1/2 cerc taper cutting 25mm	Dispozitiv chirurgical invaziv	13910
6	5E75	Mătasă neagră împletită USP 2/0	Unisil	10*75cm, fără ac	Dispozitiv chirurgical invaziv	13910
7	5F45DK26	Mătasă neagră împletită USP 3/0	Unisil	45cm, 1/2 cerc taper cutting 26mm	Dispozitiv chirurgical invaziv	13910
8	5G45DZ13	Mătasă neagră împletită USP 4/0	Unisil	45cm, 1/2 cerc corp rotund 13mm	Dispozitiv chirurgical invaziv	13910
9	8D75DZ30	Polipropilenă monofilament USP 0	Unilene	75cm, 1/2 cerc corp rotund 30mm	Dispozitiv chirurgical invaziv	13909
10	8E75DX20	Polipropilenă monofilament USP 2/0	Unilene	75cm, 1/2 cerc tăietor inversat 20mm	Dispozitiv chirurgical invaziv	13909
11	8E75CZ30	Polipropilenă monofilament USP 2/0	Unilene	75cm, 3/8 cerc corp rotund 30mm	Dispozitiv chirurgical invaziv	13909
12	8E90DZ30	Polipropilenă monofilament USP 2/0	Unilene	90cm, 1/2 cerc corp rotund 30mm	Dispozitiv chirurgical invaziv	13909
13	8G75DZ30	Polipropilenă monofilament USP 4/0	Unilene	75cm, 1/2 cerc corp rotund 30mm	Dispozitiv chirurgical invaziv	13909
14	3E45CX26	Nailon (poliamidă) monofilament USP 2/0	Unilon	45cm, ac 3/8 cerc tăietor inversat 26mm	Dispozitiv chirurgical invaziv	38000
15	3E75DZ26	Nailon (poliamidă) monofilament USP 2/0	Unilon	75cm, ac 1/2 cerc corp rotund 26mm	Dispozitiv chirurgical invaziv	38000
16	3F45CZ15	Nailon (poliamidă) monofilament USP 3/0	Unilon	45cm, ac 3/8 cerc corp rotund 15mm	Dispozitiv chirurgical invaziv	38000
17	3F75DZ16	Nailon (poliamidă) monofilament USP 3/0	Unilon	75cm, ac 1/2 cerc corp rotund 16mm	Dispozitiv chirurgical invaziv	38000
18	3G45CZ15	Nailon (poliamidă) monofilament USP 4/0	Unilon	45cm, ac 3/8 cerc corp rotund 15mm	Dispozitiv chirurgical invaziv	38000
19	3G75DZ22	Nailon (poliamidă) monofilament USP 4/0	Unilon	75cm, ac 1/2 cerc corp rotund 22mm	Dispozitiv chirurgical invaziv	38000
20	3H45CX15	Nailon (poliamidă) monofilament USP 5/0	Unilon	45cm, ac 3/8 cerc tăietor inversat 15mm	Dispozitiv chirurgical invaziv	38000
21	3H35DZ16	Nailon (poliamidă) monofilament USP 5/0	Unilon	35cm, ac 1/2 cerc corp rotund 16mm	Dispozitiv chirurgical invaziv	38000
22	6F75DZ22	Poliester împletit USP 3/0	Unibond	75cm, ac 1/2 cerc corp rotund 22mm	Dispozitiv chirurgical invaziv	13906
23	6G45CX15	Poliester împletit USP 4/0	Unibond	45cm, ac 3/8 cerc tăietor inversat 15mm	Dispozitiv chirurgical invaziv	13906
24	6G90DZ16	Poliester împletit USP 4/0	Unibond	90cm, ac 1/2 cerc corp rotund 16mm	Dispozitiv chirurgical invaziv	13906



25	6G75DZ22	Poliester împletit USP 4/0	Unibond	75cm, ac 1/2 cerc corp rotund 22mm	Dispozitiv chirurgical invaziv	13906
26	6H60DZ16	Poliester împletit USP 5/0	Unibond	60cm, ac 1/2 cerc corp rotund 16mm	Dispozitiv chirurgical invaziv	13906
27	6H75DZ17	Poliester împletit USP 5/0	Unibond	75cm, ac 1/2 cerc corp rotund 17mm	Dispozitiv chirurgical invaziv	13906

Iarvoi Petru, Director

Semnătura





## Letter of Authorization

We, Unisur Lifecare Private Limited based in No.15/1,2,3, Acharya Industrial Complex, Andrahalli Main Road, Bangalore- 560091 Karnataka, India assign FPC "SOGNO" SRL, based at, No 2 Academiei str., Chisinau, Republic of Moldova, as authorized representative in correspondence with the conditions of directive 93/42/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

For Unisur Lifecare Private Limited

For UNISUR LIFECARE PRIVATE LIMITED



Avinash P R  
Manager- Quality Assurance

Avinash PR  
Manager – Quality Assurance

Date: 08th August 2022

Place: Bangalore



**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



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.



*[Signature]*  
Dr. Katarina 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

Page 1 of 1



*Katarina Tomin Srdošová*  
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



## 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.

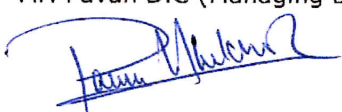
We, hereby under our sole responsibility declare that the product to which this declaration relates, is in conformity with the relevant provisions of standards and other normative document(s) and full fills the essential requirements of 93/42/EEC. We have presented our product and our system to 3EC International 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 <sup>th</sup> , 2019	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



**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: <b>BLACK BRAIDED SILK</b>			
Brand Name: <b>UNISIL, ADVAMED-SILK, MARFLOW-SILK, UNISIL FAST, M-SILK, ALPHA-SILK, I SILK, N-CARE SILK, RHIZOSILK</b>			
GMDN Code: <b>13910</b>			
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, Trocar 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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Tele: +91 9108 990 400

E-mail: info@universalsutures.com

CIN: U33110KA2015PTC078111

**Corporate Office**

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Plot No: MYS357 in Peenya Plantation, HMT Factory Main Road,

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Tele: +91 80 4166 6920

E-mail: care@universalsutures.com

www.universalsutures.com



Generic Name: MONOFILAMENT STAINLESS STEEL SUTURE			
Brand Name: MONOSTEEL, ADVAMED-STEEL, MARFLOW-STEEL, MONOSTEEL FAST, M-STEEL, ALPHA-STEEL, I STEEL, N-CARE STEEL, RHIZOSTEEL			
GMDN Code: 13904			
USP Size Min.	Metric size (Gauge No.) Max.	Needle Profile	Needle curvature
7	9	Taper point (Round body), Taper cut, Cutting, Reverse cutting, Blunt, Spatulated, Trocar point, Diamond point	1/2 Circle 1/4 Circle 3/8 Circle 5/8 Circle Straight
6	8		
5	7		
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		



**Registered Office**  
Bangalore

No. 15/1,2,3, Andrahalli Main Road, Acharya Indl. Complex  
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Tele: +91 9108 990 400  
E-mail: info@universalsutures.com  
CIN: U33110KA2015PTC078111

**Corporate Office**  
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Plot No: MYS357 in Peenya Plantation, HMT Factory Main Road,  
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www.universalsutures.com





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.



*Katarina Tomin Srdošová*  
Dr. Katarína 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,  
Vishwanedam 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, GPCLON	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

Page 1 of 1



At Bratislava, on December 27<sup>th</sup>, 2020  
Valid until May 26<sup>th</sup>, 2024

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



**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

Page 1 of 3



**Registered Office**  
 Bangalore

No. 15/1,2,3, Andrahalli Main Road, Acharya Indl. Complex  
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 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		

**Registered Office**

Bangalore

No. 15/1,2,3, Andrahalli Main Road, Acharya Indl. Complex

Vishwaneedam Post, Near Anupama School

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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

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Generic Name: MONOFILAMENT POLYPROPYLENE SUTURE			
Brand Name – UNILENE, UNILENE FAST, ADVAMED–POLYPROPYLENE, M–LENE, i Lene, N–CARE Polypropylene, RHIZOLENE, MDB-LENE, GPCLENE			
GMDN Code: 13909			
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		

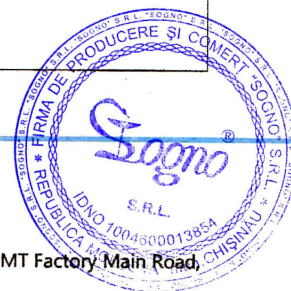
Generic Name: MONOFILAMENT POLYAMIDE SUTURE			
Brand Name –UNILON, UNILON FAST, ADVAMED–NYLON, M–LON, i Lon, N–CARE Nylon, RHIZOLON, MDB-LON, GPCLON			
GMDN Code :38000			
USP Size Min.	Metric size (Gauge No.) Max.	Needle Profile	Needle curvature
5	7	TAPER POINT (ROUND BODY), TAPER CUT, CUTTING, REVERSE 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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## Annex to the Declaration of Conformity

## Product Information:

Code	Description	Model	Class	GMDN Code
	<b>Unisil (Silk) Black</b>			
5B75DZ35	Unisil (Silk) Black USP 2	75cm, 1/2 circle taper point 35mm	IIb	13910
5C75DZ35	Unisil (Silk) Black USP 1	75cm, 1/2 circle taper point 35mm	IIb	13910
5D75DK25	Unisil (Silk) Black USP 0	75cm, 1/2 circle taper cutting 25mm	IIb	13910
5D75CK30	Unisil (Silk) Black USP 0	75cm, 3/8 circle taper cutting 30mm	IIb	13910
5E75DK25	Unisil (Silk) Black USP 2-0	75cm, 1/2 circle taper cutting 25mm	IIb	13910
5E75	Unisil (Silk) Black USP 2-0	10*75cm, without needle	IIb	13910
5F45DK26	Unisil (Silk) Black USP 3-0	45cm, 1/2 circle taper cutting 26mm	IIb	13910
5G45DZ13	Unisil (Silk) Black USP 4-0	45cm, 1/2 circle round body 13mm	IIb	13910
	<b>Unilene (Polypropylene) Blue</b>			
8D75DZ30	Unilene (Polypropylene) Blue USP 0	75cm, 1/2 circle round body 30mm	IIb	13909
8E75DX20	Unilene (Polypropylene) Blue USP 2-0	75cm, 1/2 circle reverse cutting 20mm	IIb	13909
8E75CZ30	Unilene (Polypropylene) Blue USP 2-0	75cm, 3/8 circle round body 30mm	IIb	13909
8E90DZ30	Unilene (Polypropylene) Blue USP 2-0	90cm, 1/2 circle round body 30mm	IIb	13909
8G75DZ30	Unilene (Polypropylene) Blue USP 4-0	75cm, 1/2 circle round body 30mm	IIb	13909
	<b>Unilon (Polyamide (Nylon)) Black</b>			
3E45CX26	Unilon (Monofilament Polyamide (Nylon) USP 2-0	45cm, 3/8 circle reverse cutting 26mm	IIb	38000
3E75DZ26	Unilon (Monofilament Polyamide (Nylon) USP 2-0	75cm, 1/2 circle round body 26mm	IIb	38000
3F45CZ15	Unilon (Monofilament Polyamide (Nylon) USP 3-0	45cm, 3/8 circle round body 15mm	IIb	38000
3F75DZ16	Unilon (Monofilament Polyamide (Nylon) USP 3-0	75cm, 1/2 circle round body 16mm	IIb	38000
3G45CZ15	Unilon (Monofilament Polyamide (Nylon) USP 4-0	45cm, 3/8 circle round body 15mm	IIb	38000
3G75DZ22	Unilon (Monofilament Polyamide (Nylon) USP 4-0	75cm, 1/2 circle round body 22mm	IIb	38000
3H45CX15	Unilon (Monofilament Polyamide (Nylon) USP 5-0	45cm, 3/8 circle reverse cutting 15mm	IIb	38000
3H35DZ16	Unilon (Monofilament Polyamide (Nylon) USP 5-0	35cm, 1/2 circle round body 16mm	IIb	38000
	<b>Unibond (Polyester) Braided</b>			
6F75DZ22	Unibond (Polyester) Braided USP 3-0	75cm, ac 1/2 circle round body 22mm	IIb	13906
6G45CX15	Unibond (Polyester) Braided USP 4-0	45cm, ac 3/8 circle reverse cutting 15mm	IIb	13906
6G90DZ16	Unibond (Polyester) Braided USP 4-0	90cm, ac 1/2 circle round body 16mm	IIb	13906
6G75DZ22	Unibond (Polyester) Braided USP 4-0	75cm, ac 1/2 circle round body 22mm	IIb	13906
6H60DZ16	Unibond (Polyester) Braided USP 5-0	60cm, ac 1/2 circle round body 16mm	IIb	13906
6H75DZ17	Unibond (Polyester) Braided USP 5-0	75cm, ac 1/2 circle round body 17mm	IIb	13906

For Unisur Lifecare Private Limited

Pavan D.C  
Managing Director

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