UNIVERSAL SUTURES

"HEALING BEYOND COMFORT"

UNISUR

Lifecare Pvt. Ltd.

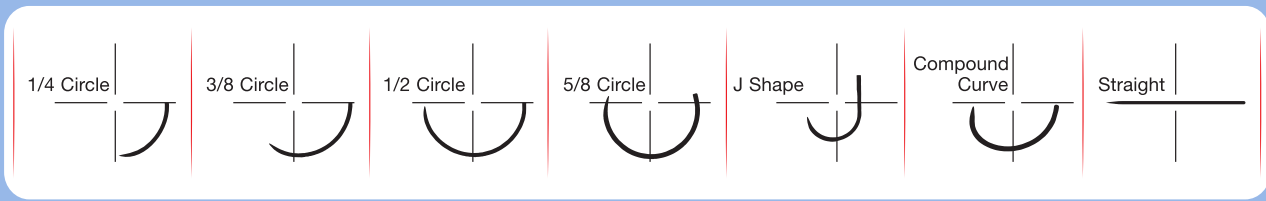
Sutures
Mesh
Bone Wax

Digitally signed by Iarovoi Petru
Date: 2021.09.16 10:45:48 EEST
Reason: MoldSign Signature
Location: Moldova

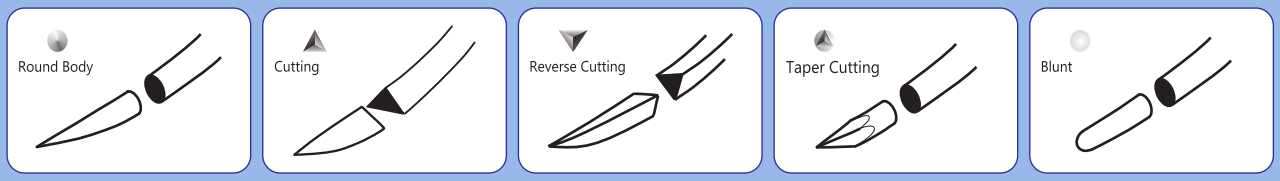
AN ISO & CE CERTIFIED SURGICAL SUTURES AND MESH MANUFACTURING COMPANY

We Manufacture complete range of Surgical Sutures, Hernia Mesh & Bonewax

Needle Shape



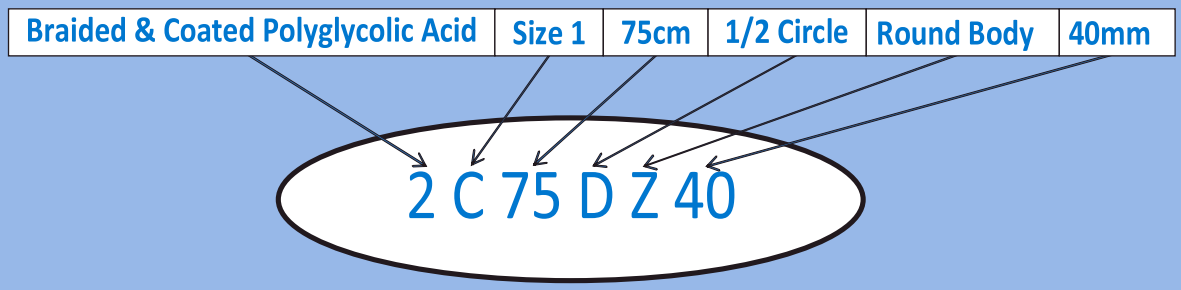
Needle Type:



International Coding Pattern

Code 1	Product	Code 2	USP Size	Code 3	Code 4	Needle Curvature	Code 5	Needle Type	Code 6
1	Braided & Coated Polyglycolic Acid Undyed	A	3	SUTURE LENGTH in cm	C	3/8 Circle	Z	Round Body / Taper Point	NEEDLE LENGTH in mm
2	Braided & Coated Polyglycolic Acid	B	2		D	1/2 Circle	Y	Cutting	
3	Monofilament Polyamide (Nylon)	C	1		A	Straight	X	Reverse Cutting	
4	Catgut Chromic	D	0		E	5/8 Circle	K	Taper Cutting	
5	Black Braided Silk	E	2-0				T	Trocar Point	
6	Braided Polyester	F	3-0				R	Blunt Point	
7	Catgut Plain	G	4-0				S	Spatula	
8	Monofilament Polypropylene	H	5-0						
9	Monofilament Polydioxanone	I	6-0						
10	Braided & Coated Polyglactin 910	J	7-0						
11	Monofilament Polyglecaprone 25	K	8-0						
12	Braided & Coated Polyglactin 910 Undyed								

Example:



UNISIL

Black Braided Silk
Non Absorbable Surgical Suture U.S.P.

UNISIL – Black Braided Silk Suture is a non absorbable, sterile, surgical suture composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx mori (B. Mori) of the family Bombycidae.

UNISIL sutures are processed to remove the natural waxes and gums. UNISIL suture is dyed black and coated with a special wax mixture. UNISIL Black Braided Silk is also available in its natural color.

UNISIL Virgin silk is available in which the sericin gum is not removed and serves to hold the filaments together.

In-house needle manufacturing provides you the better needles with optimum sharpness which finally delivers smooth riding on tissues during suturing.

Indications:

Black Braided Silk Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

- Highest purified protein from Species B. Mori results no tissue reaction
- Beeswax coated ultra smooth surface decrease suturing timing followed by no tissue trauma
- Unmatched Knot strength provides satisfaction to user
- USP approved dye increases visibility followed by no reaction

Best Used By:

- Orthopaedic Surgeons,
- General Surgeons,
- Gynaecologists,
- Cardiac Surgeons,
- Endoscopic Surgeons

Ultimate Suture For:

- Skin Closure
- Hard Tissues approximation
- Tendon Repair
- Muscles approximation

Additional Information:

Suture Characteristics	:	Non Absorbable Surgical Suture
Type	:	Braided
Material	:	Braided Silk
Color	:	Black
Absorption	:	Non Absorbable
USP Range	:	5/0 – 2
Sterilization	:	EO (Ethylene Oxide)
Shelf Life	:	5 Years
Product Characteristics	:	Excellent tensile strength, Excellent knot tying, Minimum tissue reaction.
Packaging	:	In food grade folder packed in a medical grade pouch, with or without needle
Needle Type	:	Round bodied, cutting edge, taper point, straight, blunt point
MFG. LIC No	:	MFG/MD/2020/000109
OEM. LIC No	:	N. Code: KA/DEVICE/MFG/MD/2020/000109

UNISIL

Black Braided Silk
Non Absorbable Surgical Suture U.S.P.

Code No.	SUTURE		NEEDLE DESCRIPTION
	USP SIZE	LENGTH	
5E75CY26	2-0	75 cm	3/8 Circle Cutting
5E75CX24	2-0	75 cm	3/8 Circle Reverse Cutting
5E12X60	2-0	12x60	Without Needle
5D75CY40	0	75 cm	3/8 Circle Cutting
5C75CY40	1	75 cm	3/8 Circle Cutting
5E13X60	2-0	13x60	Without Needle
5G75CZ16	4-0	75 cm	3/8 Circle Round Bodied 16mm
5F75DZ30	3-0	75 cm	1/2 Circle Round Bodied 30mm
5F60	3-0	60 cm	Without Needle
5D60	0	60 cm	Without Needle
5F75CX19	3-0	75 cm	3/8 Circle Reverse Cutting 19mm
5F75CX25	3-0	75 cm	3/8 Circle Reverse Cutting 25mm
5F75CX30	3-0	75 cm	3/8 Circle Reverse Cutting 30mm
5F75DX25	3-0	75 cm	1/2 Circle Reverse Cutting 25mm
5F75DZ26	3-0	75 cm	1/2 Circle Taper Point 26mm
5F75DX30	3-0	75 cm	1/2 Circle Reverse Cutting 30mm
5E75DZ22	2-0	75 cm	1/2 Circle Taper Point 22mm
5E75DZ30	2-0	75 cm	1/2 Circle Taper Point 30mm
5E75CZ30	2-0	75 cm	3/8 Circle Reverse Cutting 40mm
5D75DZ26	0	75 cm	1/2 Circle Taper Point 26mm
5D75DZ35	0	75 cm	1/2 Circle Taper Point 35mm
5F45DZ26	3-0	45 cm	1/2 Circle Taper Point 26mm
5E75DZ25	2-0	75 cm	1/2 Circle Taper Point 25mm
5D75DZ25	0	75 cm	1/2 Circle Taper Point 25mm
5F75	3-0	75 cm	Without Needle
5D60	0	60 cm	Without Needle

CERTIFICATES

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

EC CERTIFICATE
No. 2016-MDD/QS-028

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 III,

Absorbable Surgical Suture
Brand Name: UNIGLYDE, UNIGLYDE MONO, UNISYNTH, UNISYNTH PDS
(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, approved and 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. 310216 and the Final protocol No. 310216/2016 that is enclosed to this certificate.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced models of medical devices 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 November 6th, 2021 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. For the placing on the market of the above referenced models of medical devices covered by this certificate, an EC design-examination certificate according to the Directive 93/42/EEC as amended by 2007/47/EC, Annex II (4) is required.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

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

In Bratislava, on November 7th, 2016

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

EC CERTIFICATE
No. 2016-MDD/QS-030

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,

Non-absorbable Surgical Suture
Brand Name: UNIBOND, UNILENE, UNILON

Monofilament Polypropylene Mesh
Brand Name: UNILENE MESH
(for detailed list refer to Annex; pages 1 to 2)

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. 310216, and the Final protocol No. 310216/2016 that is enclosed to this certificate.

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 November 6th, 2021 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.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

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

In Bratislava, on November 7th, 2016

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

EC DESIGN-EXAMINATION CERTIFICATE
No. 2016-MDD/DE-029

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

Absorbable Surgical Suture
Brand Name: UNIGLYDE, UNIGLYDE MONO, UNISYNTH, UNISYNTH PDS
(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

conforms with the relevant provisions of Annex II.4 of the Directive 93/42/EEC on medical devices as transposed into national legislation. The device fulfils the essential requirements specified in Annex I of the Directive 93/42/EEC taking into account intended use of the device.

The Notified Body No. 2265 has performed a design-examination of the device according to Annex II.4 of the Directive 93/42/EEC. The detailed device description, design dossier and evaluation of the examination are presented in the Final protocol No. 310216/2016 that is enclosed to this certificate.

This certificate is issued under the following conditions:

It applies only to the design of the above referenced model of the medical device and it does not imply the Notified Body executed any surveillance or control of its manufacture. The manufacturer is obligated to assure that all medical devices of the respective model conform to the type whose design has been approved by this certificate. The certificate remains valid until the approved design is changed but till November 6th, 2021 at the latest. This EC design-examination certificate is complementary to an EC Certificate, approving the manufacturer's quality system according to the Directive 93/42/EEC as amended by 2007/47/EC, Annex II excluding (4).

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

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

In Bratislava, on November 7th, 2016

SNAS Reg. No. 305/Q-054

CERTIFICATE

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

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

UNIVERSAL SUTURES

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-0387/18 **Date of issuance: November 29th, 2018** **Original date of approval: November 1st, 2016**

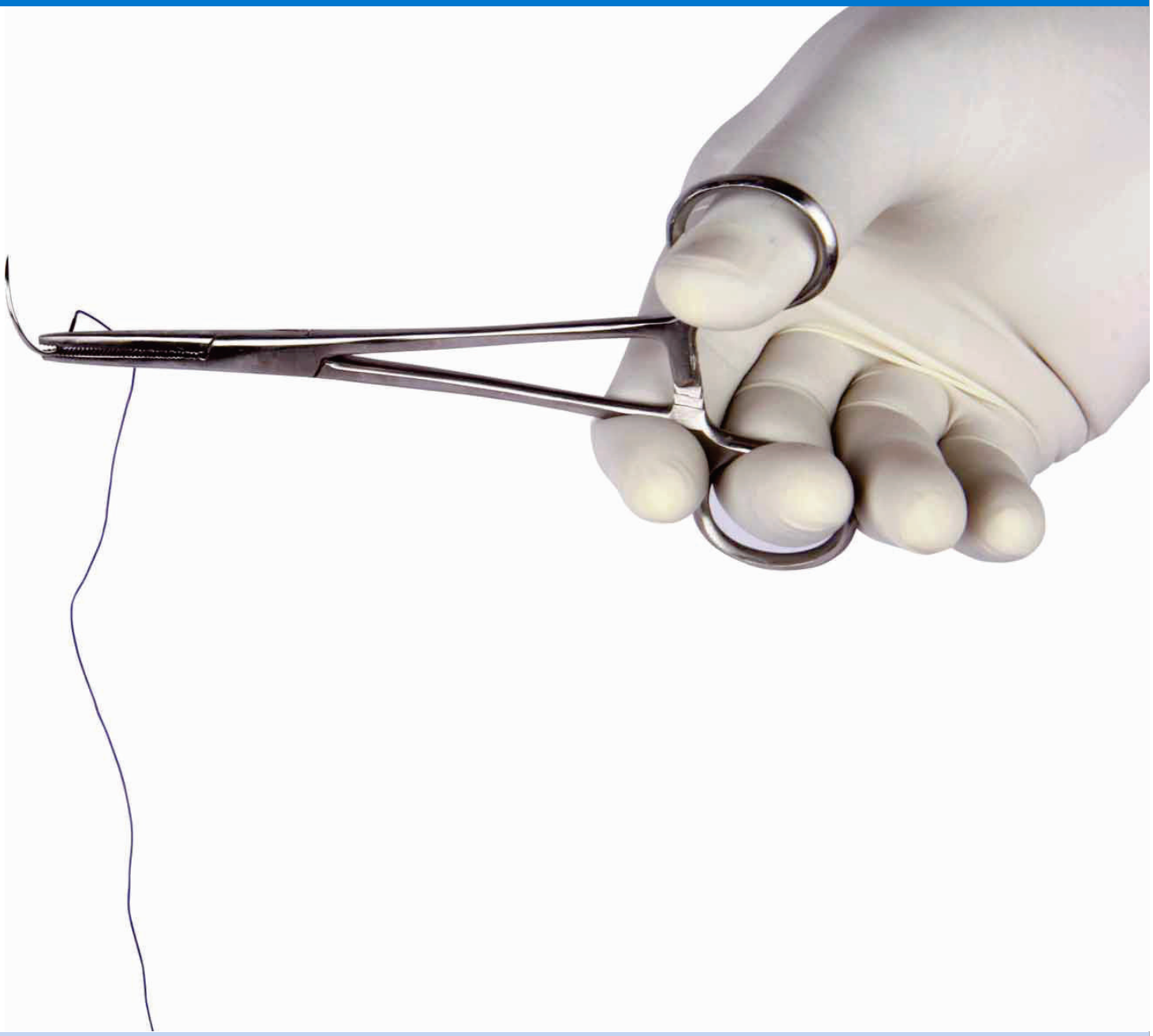
This certificate is valid from **November 29th, 2018** to **October 31st, 2019** on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

This certificate fully supersedes previous certificate No. M-0387/16 issued on November 1st, 2016.

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

Dr. Katarína 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.



REGISTERED OFFICE :

UNISUR LIFECARE PVT. LTD.

No. 15/1,2,3 Andhrahalli Main Road, Acharya Indl. Complex,
Vishwaneedam Post, Near Anupama School,
BANGALORE - 560091 Karnataka, INDIA
Tel.: +91 9108 990 400 |
E-Mail: info@universalsutures.com | Web.: www.universalsutures.com

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