

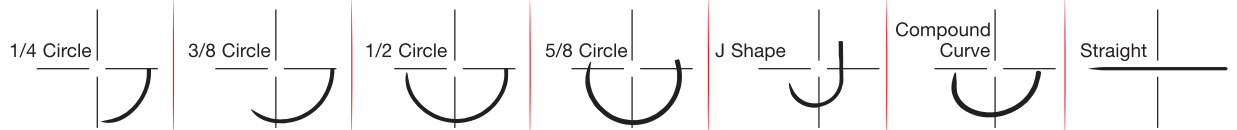
UNIVERSAL SUTURES
"HEALING BEYOND COMFORT"



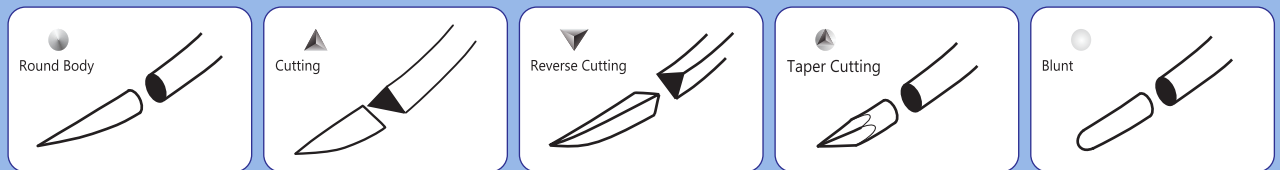
Sutures
Mesh
Bone Wax

AN ISO & CE CERTIFIED SURGICAL SUTURES AND MESH MANUFACTURING COMPANY
We Manufacture complete range of Surgical Sutures, Hernia Mesh & Bonewax

Needle Shape



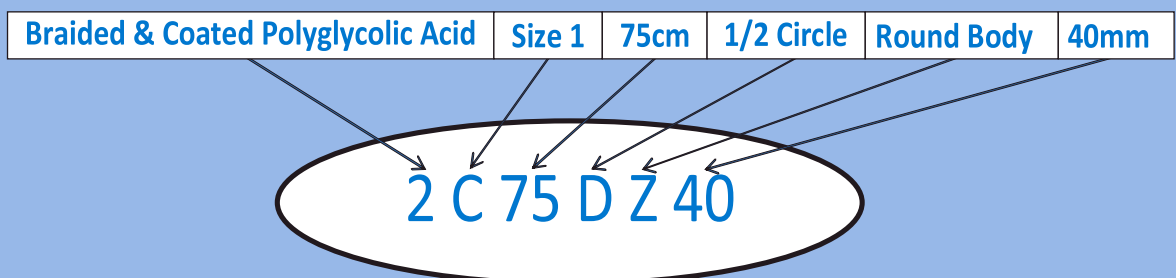
Needle Type:



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 Polyglcaprone 25	K	8-0						
12	Braided & Coated Polyglactin 910 Undyed								

Example:



UNILENE

Monofilament Polypropylene
Non-Absorbable Suture (U.S.P.)



WHEN LIFE
depends on
THREAD

www.universalsutures.com

UNILENE

Monofilament Polypropylene

Non Absorbable Surgical Suture U.S.P.



UNILENE – Monofilament Polypropylene Suture is a non absorbable sterile surgical suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The suture is pigmented blue to enhance visibility.

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

Indications:

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

- Smooth Surface results minimal tissue trauma
- Being a monofilament with smooth surface never support bacterial growth followed by capillary action
- Uniform elasticity supports small movements results cosmetic effect
- Ultra smooth surface results negligible pain
- Blue pigmentation enhances visibility

Best Used By:

- General Surgeons,
- Gynaecologists,
- Orthopaedics,
- Cardiac Surgeons,
- Endoscopic Surgeons

Ultimate Suture For:

- Skin Closure
- Hard Tissues approximation
- Ligament Repair
- Mesh Fixation

Additional Information:

Suture Characteristics	:	Non Absorbable Surgical Suture
Type	:	Monofilament
Material	:	Polypropylene
Color	:	Blue
Absorption	:	Non Absorbable
USP Range	:	6/0 – 1
Shelf Life	:	5 Years
Sterilization	:	EO (Ethylene Oxide)
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

UNILENE

Monofilament Polypropylene
Non Absorbable Surgical Suture U.S.P.



Code No.	SUTURE		NEEDLE DESCRIPTION
	USP SIZE	LENGTH	
8I90DZ13DA	6-0	90 cm	1/2 Circle Round Body 13mm Double Armed
8H90DZ16DA	5-0	90 cm	1/2 Circle Round Body 16mm Double Armed
8G90DZ17DA	4-0	90 cm	1/2 Circle Round Body 17mm Double Armed
8F90DZ26DA	3-0	90 cm	1/2 Circle Round Body 26mm Double Armed
8E90DZ20DA	2-0	90 cm	1/2 Circle Round Body 20mm Double Armed
8E90DZ26DA	2-0	90 cm	1/2 Circle Round Body 26mm Double Armed

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. 562/2008 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

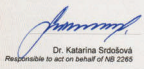
Unisur Lifecare Private Limited
No. 15/1, 2, 3, Andrahalli Main Road, Acharya Industrial Complex,
Vishwaneedam Post, 560 091 Bangalore, Karnataka, India

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 fulfillment 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.

 
Dr. Katarína Štrdiová
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. 562/2008 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 fulfillment of relevant legal and other requirements by manufacturer.

 
Dr. Katarína Štrdiová
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. 562/2008 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

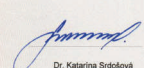
Unisur Lifecare Private Limited
No. 15/1, 2, 3, Andrahalli Main Road, Acharya Industrial Complex,
Vishwaneedam Post, 560 091 Bangalore, Karnataka, India

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).

 
Dr. Katarína Štrdiová
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

CERTIFICATE

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

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

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

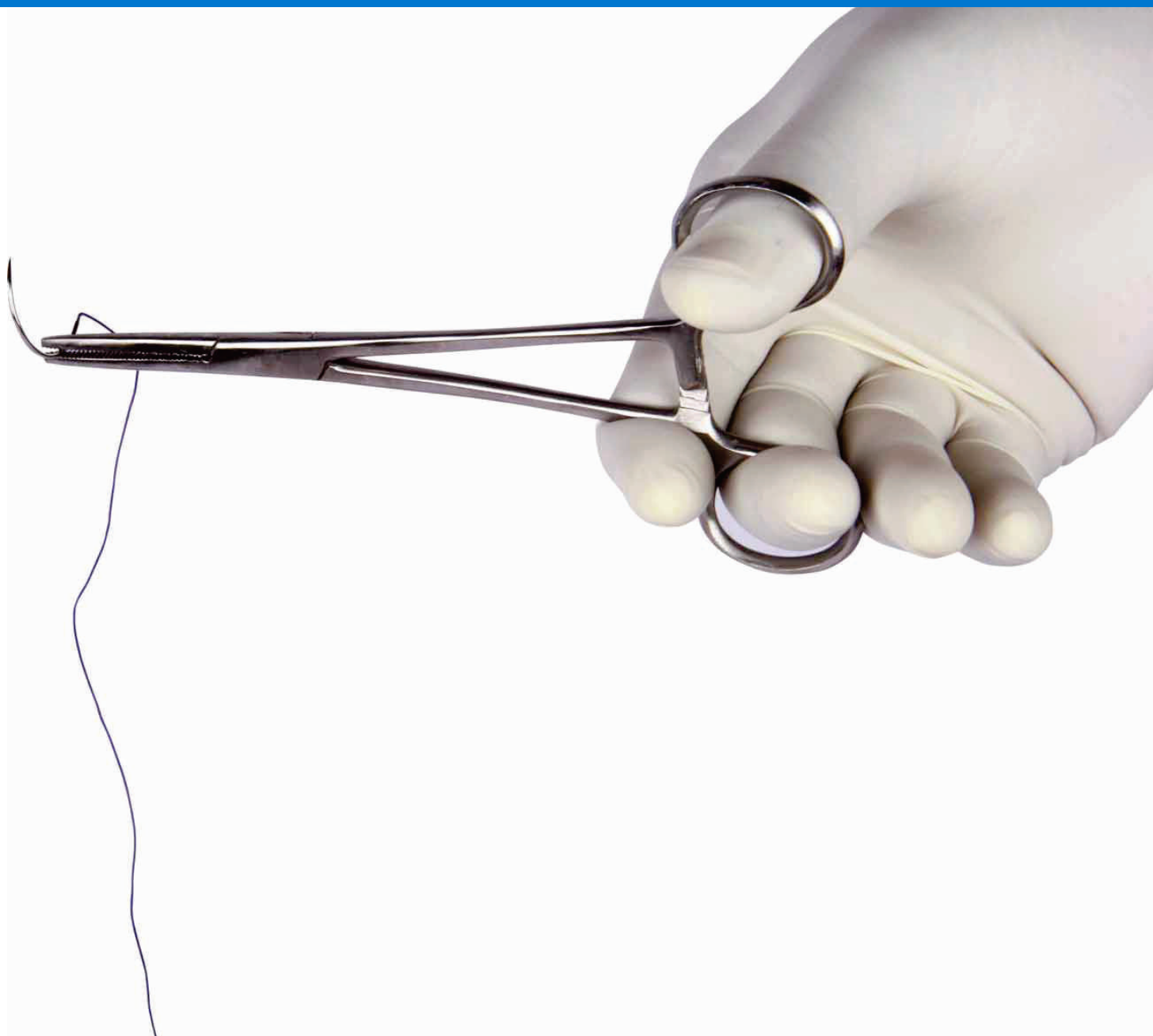
Certificate No.: M-038718 Date of issuance: November 29th, 2018 Original date of approval: November 1st, 2016

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-038716 issued on November 1st, 2016.

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

 
Dr. Katarína Štrdiová
Unisur Lifecare Private Limited

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/G-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

CORPORATE OFFICE :

UNISUR LIFECARE PVT. LTD.

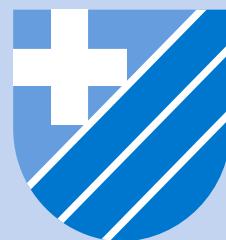
Unit No. 303, 3rd Floor, Brigade Rubix,

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

BANGALORE - 560013 Karnataka, INDIA

Tel.: +91 9108 990 400 |

E-Mail: care@universalsutures.com | Web.: www.universalsutures.com



UNISUR
Lifecare Pvt. Ltd.

CE EN ISO 13485
2265

NSIC