

Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale

nr. 62 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 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



Semnătura

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. 7599 din 02.10.2023
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Clara Techi Dionisie
Semnătura persoanei responsabile	CDS

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. **352¹**, 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 absorbabilă)"

Sunt autentice și corespund realității.



Iarovoi Petru, Director

Semnătura

Data: 02.10.2023

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. 352¹, 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 absorbabilă)"

Sunt autentice și corespund realității.



Iarovoi Petru, Director

Semnătura

Data: 02.10.2023

Lista dispozitivelor medicale UNISUR Lifecare (Sutură absorbabilă)

Nr d/o	Numărul de catalog	Denumire	Denumirea comercială	Model	Tip dispozitiv	GMDN Code
1	2D75DZ45	Acid Poliglicolic USP 0	Uniglyde	75cm, 1/2 cerc corp rotund 45mm	Dispozitiv chirurgical invaziv	13908
2	2E70CX36	Acid Poliglicolic USP 2/0	Uniglyde	70cm, 3/8 cerc tăietor inversat 36mm	Dispozitiv chirurgical invaziv	13908
3	2F75DZ26DA	Acid Poliglicolic USP 3/0	Uniglyde	75cm, double armed, 1/2 cerc taper point 26mm	Dispozitiv chirurgical invaziv	13908
4	2G75DZ48	Acid Poliglicolic USP 4/0	Uniglyde	75cm, 1/2 cerc corp rotund 48mm	Dispozitiv chirurgical invaziv	13908
5	1G75CX18	Acid Poliglicolic Rapid USP 4/0	Uniglyde Fast	75cm, 3/8 cerc tăietor inversat 18mm	Dispozitiv chirurgical invaziv	13908
6	1H75CX12	Acid Poliglicolic Rapid USP 5/0	Uniglyde Fast	75cm, 3/8 cerc tăietor inversat 12mm	Dispozitiv chirurgical invaziv	13908
7	10C75DZ36	Poliglactină 910 USP 1	Unisynth	75cm, 1/2 cerc corp rotund 36mm	Dispozitiv chirurgical invaziv	17471
8	10D75DZ36	Poliglactină 910 USP 0	Unisynth	75cm, 1/2 cerc corp rotund 36mm	Dispozitiv chirurgical invaziv	17471
9	10F75DK37	Poliglactină 910 USP 3/0	Unisynth	75cm, 1/2 cerc taper cutting 37mm	Dispozitiv chirurgical invaziv	17471
10	11F70EZ26DA	Poliglecapron 25 USP 3/0	Uniglyde Mono	70cm, double armed, 5/8 cerc corp rotund 26mm	Dispozitiv chirurgical invaziv	17246
11	9F75CK25	Polidioxanonă USP 3/0	Unisynth PDS	75cm, 3/8 cerc taper cutting 25mm	Dispozitiv chirurgical invaziv	16584
12	9G75CX15	Polidioxanonă USP 4/0	Unisynth PDS	75cm, 3/8 cerc tăietor inversat 15mm	Dispozitiv chirurgical invaziv	16584
13	9G75CK17	Polidioxanonă USP 4/0	Unisynth PDS	75cm, 3/8 cerc taper cutting 17mm	Dispozitiv chirurgical invaziv	16584
14	9G90DZ20DA	Polidioxanonă USP 4/0	Unisynth PDS	90cm, double armed, 1/2 cerc corp rotund 20mm	Dispozitiv chirurgical invaziv	16584
15	9G75CX24	Polidioxanonă USP 4/0	Unisynth PDS	75cm, 3/8 cerc tăietor inversat 24mm	Dispozitiv chirurgical invaziv	16584
16	9H75CK17	Polidioxanonă USP 5/0	Unisynth PDS	75cm, 3/8 cerc taper cutting 17mm	Dispozitiv chirurgical invaziv	16584
17	9I70DZ13	Polidioxanonă USP 6/0	Unisynth PDS	70cm, 1/2 cerc corp rotund 13mm	Dispozitiv chirurgical invaziv	16584

Iarovoi 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. 2020-MDD/QS-133

issued in compliance with the Council Directive 93/42/EEC as amended,
certifies that the medical device of Class III,

Sterile 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, approved and 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. 310505/2020.

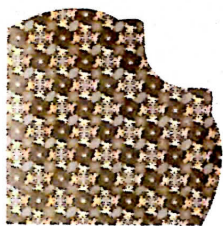
This certificate is issued under the following conditions:

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 May 26th, 2024 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, Annex II (4) is required.



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

At Bratislava, on December 27th, 2020
This certificate supersedes the EC Certificate No. 2016-MDD/QS-028/A issued on November 14th, 2019





ANNEX TO EC CERTIFICATE No. 2020-MDD/QS-133

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 Absorbable Surgical Suture

Generic Name	Brand Name (s)	USP Size
Polyglycolic Acid Suture	UNIGLYDE, UNIGLYDE FAST, ADVAMED-PGA, ADVAMED-PGA FAST, M-GLYDE, M-GLYDE FAST, i Glyde, i Glyde Fast, N-CARE PGA, N-CARE PGA Fast, RHIZOGLYDE, RHIZOGLYDE FAST, MDB-GLYDE, MDB-GLYDE FAST, UNILOOP-PGA, GPCGLYDE, GPCGLYDE FAST	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4
Polyglactin 910 Suture	UNISYNTH, UNISYNTH FAST, ADVAMED-PGLA, ADVAMED-PGLA FAST, M-SYNTH, M-SYNTH FAST, M-CRYL, M-CRYL FAST, i Synth, i Synth Fast, N-CARE PGLA, N-CARE PGLA Fast, RHIZOCRYL, RHIZOCRYL FAST, MEDICRYL, MEDICRYL FAST, MDB-GLACTIN 910, MDB-GLACTIN 910 FAST, UNILOOP-PGLA, GPCSYNTH, GPCSYNTH FAST	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4
Polydioxanone Suture	UNISYNTH PDS, UNISYNTH PDS FAST, ADVAMED-PD, M-PDS, i Synth PD, N-CARE PDS, RHIZOPDS, MDB-PDS, UNILOOP-PDS, GPCSYNTH PDS	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4
Poliglecaprone 25 Suture	UNIGLYDE MONO, UNIGLYDE MONO FAST, ADVAMED-POLIGLECAPRONE, M-MONO, i Glyde Mono, N-CARE MONO, RHIZOMONO, MDB-MONO, GPCGLYDE MONO	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4

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Dr. Katarina Tomin Srdošová
Responsible to act on behalf of NB 2285

At Bratislava, on December 27th, 2020
Valid until May 26th, 2024



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

EC DESIGN-EXAMINATION CERTIFICATE

No. 2020-MDD/DE-134

issued in compliance with the Council Directive 93/42/EEC as amended,
certifies that the design of medical device of Class III,

Sterile 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

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

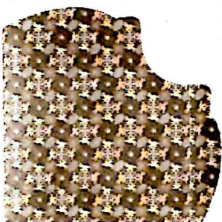
The Notified Body No. 2265 has performed a design-examination of the device according to Annex II.4 of the Directive 93/42/EEC as amended. The detailed device description, design dossier and evaluation of the examination are presented in the Final protocol No. 310505/2020.

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 May 26th, 2024 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, Annex II (excluding 4).



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



At Bratislava, on December 27th, 2020
This certificate supersedes the EC Design-Examination Certificate No. 2016-MDD/DE-029/A issued on November 14th, 2019



ANNEX TO EC DESIGN-EXAMINATION CERTIFICATE No. 2020-MDD/DE-134

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 Design-Examination Certificate:

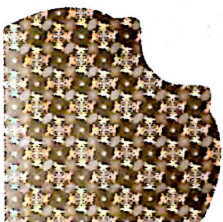
Product name: Sterile Absorbable Surgical Suture

Generic Name	Brand Name (s)	USP Size
Polyglycolic Acid Suture	UNIGLYDE, UNIGLYDE FAST, ADVAMED-PGA, ADVAMED-PGA FAST, M-GLYDE, M-GLYDE FAST, i Glyde, i Glyde Fast, N-CARE PGA, N-CARE PGA Fast, RHIZOGLYDE, RHIZOGLYDE FAST, MDB-GLYDE, MDB-GLYDE FAST, UNILoop-PGA, GPCGLYDE, GPCGLYDE FAST	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4
Polyglactin 910 Suture	UNISYNTH, UNISYNTH FAST, ADVAMED-PGLA, ADVAMED-PGLA FAST, M-SYNTH, M-SYNTH FAST, M-CRYL, M-CRYL FAST, i Synth, i Synth Fast, N-CARE PGLA, N-CARE PGLA Fast, RHIZOCRYL, RHIZOCRYL FAST, MEDICRYL, MEDICRYL FAST, MDB-GLACTIN 910, MDB-GLACTIN 910 FAST, UNILoop-PGLA, GPCSYNTH, GPCSYNTH FAST	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4
Polydioxanone Suture	UNISYNTH PDS, UNISYNTH PDS FAST, ADVAMED-PD, M-PDS, i Synth PD, N-CARE PDS, RHIZOPDS, MDB-PDS, UNILoop-PDS, GPCSYNTH PDS	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4
Poliglecaprone 25 Suture	UNIGLYDE MONO, UNIGLYDE MONO FAST, ADVAMED-POLIGLECAPRONE, M-MONO, i Glyde Mono, N-CARE MONO, RHIZOMONO, MDB-MONO, GPCGLYDE MONO	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4

Page 1 of 1



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



At Bratislava, on December 27th, 2020
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 ABSORBABLE SURGICAL SUTURES**
 Classification and Justification : Refer Page 2 of 5
 Model/Type ref. : Refer Page 2 to 5
 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 fulfills the essential requirements of 93/42/EEC.

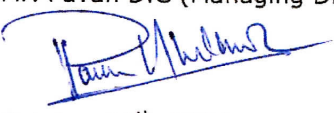
We have presented our product and our system to 3EC International a.s, (Notified Body Number 2265) addressed at Hraničná 18, 82105 Bratislava, for conformity assessment as per Annex II including section IV of MDD 93/42/EEC as amended by 2007/47/EC.

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 11737-2: 2020
- b) Non- Harmonized Standards: ISO/TR 20416:2020
- c) Technical File. (USPL-TCF-MD-01)

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

CERTIFICATE	DATE OF ISSUE	CERTIFICATE VALIDITY
EC CERTIFICATE: 2020-MDD/QS-133	December 27 th , 2020	May 26 th , 2024
EC DESIGN EXAMINATION CERTIFICATE: 2020-MDD/DE- 134		

Place of Issue : Bangalore
 Manufacturer : **UNISUR LIFECARE PRIVATE LIMITED**
 Name : Mr. Pavan D.C (Managing Director)
 Signature : 
 Date : October 18th, 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 III Medical Device. [To have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III]

Generic Name: BRAIDED & COATED POLYGLYCOLIC ACID SUTURE			
Brand Names – UNIGLYDE, UNIGLYDE FAST, ADVAMED–PGA, ADVAMED–PGA FAST, M–GLYDE, M–GLYDE FAST, i Glyde, i Glyde Fast, N–CARE PGA, N–CARE PGA Fast, RHIZOGLYDE, RHIZOGLYDE FAST, MDB-GLYDE, MDB-GLYDE FAST, UNILoop-PGA, GPCGLYDE, GPCGLYDE FAST			
GMDN Code: 13908			
USP Size Min.	Metric size (Gauge No.) Max.	Needle Profile*	Needle curvature
4	6	TAPER POINT (ROUND BODY), TAPER CUT, CUTTING, REVERSE CUTTING, BLUNT, SPATULATED, TROCAR POINT, DIAMOND POINT	½ CIRCLE
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
Bangalore-560091 Karnataka, INDIA

Tele: +91 9108990400

E-mail: info@universalsutures.com

CIN: U33110KA2015PTC078111

Corporate Office

Bangalore

UnitNo.303,3rdfloor, Brigade Rubix,
Plot No.: MYS357inPeenyaPlantation, HMT Factory Main Road,
Bangalore-560013, Karnataka, INDIA

Tele: +91 8041666920

E-mail: care@universalsutures.com www.universalsutures.com

Generic Name: BRAIDED & COATED POLYGLACTIN 910 SUTURE			
Brand Name – UNISYNTH, UNISYNTH FAST, ADVAMED–PGLA, ADVAMED–PGLA FAST, M–SYNTH, M–SYNTH FAST, M–CRYL, M–CRYL FAST, i Synth, i Synth Fast, N–CARE PGLA, N–CARE PGLA Fast, RHIZOCRYL, RHIZOCRYL FAST, MEDICRYL, MEDICRYL FAST, MDB–GLACTIN 910, MDB–GLACTIN 910 FAST, UNILoop–PGLA, GPCSYNTH, GPCSYNTH FAST			
GMDN Code: 17471			
USP Size Min.	Metric size (Gauge No.) Max.	Needle Profile*	Needle curvature
4	6	TAPER POINT (ROUND BODY), TAPER CUT, CUTTING, REVERSE CUTTING, BLUNT, SPATULATED, TROCAR POINT, DIAMOND POINT	½ CIRCLE
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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Tele: +91 9108 990 400
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Corporate Office
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Tele: +91 80 4166 6920
E-mail: care@universalsutures.com
www.universalsutures.com

Generic Name: MONOFILAMENT POLYGLECAPRONE 25 SUTURE			
Brand Name -UNIGLYDE MONO, UNIGLYDE MONO FAST, ADVAMED-POLIGLECAPRONE, M-MONO, i Glyde Mono, N-CARE MONO, RHIZOMONO, MDB-MONO, GPCGLYDE MONO			
GMDN Code: 17246			
USP Size Min.	Metric size (Gauge No.) Max.	Needle Profile*	Needle curvature
4	6	TAPER POINT (ROUND BODY),	
3	6	TAPER CUT,	
2	5	CUTTING,	½ CIRCLE
1	4	REVERSE CUTTING,	¼ CIRCLE
0	3.5	BLUNT,	3/8CIRCLE
2-0	3	SPATULATED,	5/8 CIRCLE
3-0	2	TROCAR POINT,	STRAIGHT
4-0	1.5	DIAMOND POINT	
5-0	1		
6-0	0.7		
7-0	0.5		
8-0	0.4		



Registered Office

Bangalore
 No.15/1,2,3 Andrahalli Main Road, Acharya Indl. Complex
 Vishwaneedam Post, Near Anupama School
 Bangalore-560091 Karnataka, INDIA
 Tele: +91 9108990400
 E-mail: info@universalsutures.com
 CIN: U33110KA2015PTC078111

Corporate Office

Bangalore
 UnitNo.303,3rdfloor, Brigade Rubix,
 Plot No.: MYS357inPeenyaPlantation, HMT Factory Main Road,
 Bangalore-560013, Karnataka, INDIA
 Tele: +91 8041666920
 E-mail: care@universalsutures.com www.universalsutures.com

Generic Name: MONOFILAMENT POLYDIOXANONE SUTURE			
Brand Name: UNISYNTH PDS, UNISYNTH PDS FAST, ADVAMED-PD, M-PDS, i Synth PD, N-CARE PDS, RHIZOPDS, MDB-PDS, UNILoop-PDS, GPCSYNTH PDS			
GMDN Code:16584			
USP Size Min.	Metric size (Gauge No.) Max.	Needle Profile*	Needle curvature
4	6	TAPER POINT (ROUND BODY), TAPER CUT, CUTTING, REVERSE CUTTING, BLUNT, SPATULATED, TROCAR POINT, DIAMOND POINT	¼ CIRCLE ¼ CIRCLE 3/8CIRCLE 5/8 CIRCLE STRAIGHT
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		



Registered Office

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Date:28th September 2023

Annex to the Declaration of Conformity

Product Information:

Code	Description	Model	Class	GMDN Code
Uniglyde (Polyglycolic Acid) Violet				
2D75DZ45	Uniglyde (Polyglycolic Acid) Violet USP 0	75cm, 1/2 circle round body 45mm	III	13908
2E70CX36	Uniglyde (Polyglycolic Acid) Violet USP 2-0	70cm, 3/8 circle reverse cutting 36mm	III	13908
2F75DZ26DA	Uniglyde (Polyglycolic Acid) Violet USP 3-0	75cm, double armed, 1/2 circle taper point 26mm	III	13908
2G75DZ48	Uniglyde (Polyglycolic Acid) Violet USP 4-0	75cm, 1/2 circle round body 48mm	III	13908
Uniglyde Fast (Polyglycolic Acid) Undyed				
1G75CX18	Uniglyde Fast (Polyglycolic Acid) Undyed USP 4-0	75cm, 3/8 circle reverse cutting 18mm	III	13908
1H75CX12	Uniglyde Fast (Polyglycolic Acid) Undyed USP 5-0	75cm, 3/8 circle reverse cutting 12mm	III	13908
1H75DZ16	Uniglyde Fast (Polyglycolic Acid) Undyed USP 5-0	75cm, 1/2 circle round bodied 16mm	III	13908
Unisynth (Polyglactin 910) Violet				
10C75DZ36	Unisynth (Polyglactin 910) Violet USP 1	75cm, 1/2 circle round body 36mm	III	17471
10D75DZ36	Unisynth (Polyglactin 910) Violet USP 0	75cm, 1/2 circle round body 36mm	III	17471
10F75DK37	Unisynth (Polyglactin 910) Violet USP 3-0	75cm, 1/2 circle taper cutting 37mm	III	17471
Uniglyde Mono (Poliglecaprone) Violet				
11F70EZ26DA	Uniglyde Mono (Poliglecaprone 25) Violet USP 3-0	70cm, double armed, 5/8 circle round body 26mm	III	17246
Unisynth PDS (Polydioxanone) Violet				
9F75CK25	Unisynth PDS (Polydioxanone) Violet USP 3-0	75cm, 3/8 circle taper cutting 25mm	III	16584
9G75CX15	Unisynth PDS (Polydioxanone) Violet USP 4-0	75cm, 3/8 circle reverse cutting 15mm	III	16584
9G75CK17	Unisynth PDS (Polydioxanone) Violet USP 4-0	75cm, 3/8 circle taper cutting 17mm	III	16584
9G90DZ20DA	Unisynth PDS (Polydioxanone) Violet USP 4-0	90cm, double armed, 1/2 circle round body 20mm	III	16584
9G75CX24	Unisynth PDS (Polydioxanone) Violet USP 4-0	75cm, 3/8 circle reverse cutting 24mm	III	16584
9H75CK17	Unisynth PDS (Polydioxanone) Violet USP 5-0	75cm, 3/8 circle taper cutting 17mm	III	16584
9I70DZ13	Unisynth PDS (Polydioxanone) Violet USP 6-0	70cm, 1/2 circle round body 13mm	III	16584

For Unisur Lifecare Private Limited



Pavan D.C
Managing Director



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