3EC International

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.

Digitally signed by Iarovoi Petru
Date: 2022.11.16 16:21:31 EET
Reason: MoldSign Signature
Location: Moldova

Notified body
3EC International
NB 2265
NOTIFIKOVANÁ OSOBA

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

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

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

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).

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

Dr. Katarína 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

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

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

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

Unisur Lifecare Private Limited
No. 15/1,2,3 Acharya Industrial Complex,
Andrahalli Main Road Vishwaneedam Post ,
Bengaluru (Bangalore) Urban, Karnataka, 560091,
India

Attn. Mr. Pavan D C/ Managing director

Our reference	***Contact person***	BRATISLAVA
MIT/2024/P037	Michal Tomin / +421 915 366 774	25.1.2024

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as amended as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **3EC International a.s.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2265 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Unisur Lifecare Private Limited
No. 15/1,2,3 Acharya Industrial Complex,
Andrahalli Main Road Vishwaneedam Post ,
Bengaluru (Bangalore) Urban, Karnataka, 560091,
India

SRN Number (if available): IN-MF-000008184

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

3EC International a.s. 4
Hraničná 18, 821 05 Bratislava
Slovak Republic
ID No.: 36 789 003
VAT No.: SK2022390073

Katarína Tomin Srdošová, PhD.
Director of NB2265

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile Absorbable Surgical Suture Generic Name: Braided & Coated Polyglycolic Acid Suture Brand Name: 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	Class III	Generic Name: Polyglycolic Acid Suture renamed to Generic Name: Braided & Coated Polyglycolic Acid Suture	2020-MDD/QS-133; NB2265 2020-MDD/DE-134; NB2265
Sterile Absorbable Surgical Suture 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 –	Class III	Generic Name: Polyglactin 910 Suture renamed to Generic Name: Braided & Coated Polyglactin 910 Suture	2020-MDD/QS-133; NB2265 2020-MDD/DE-134; NB2265

CARE PGLA Fast, RHIZOCRYL, RHIZOCRYL FAST, MEDICRYL, MEDICRYL FAST, MDB-GLACTIN 910, MDB GLACTIN 910 FAST, UNILOOP-PGLA, GPCSYNTH, GPCSYNTH FAST			
Sterile Absorbable Surgical Suture Generic name: Monofilament Poliglecaprone 25 Suture Brand Name: UNIGLYDE MONO, UNIGLYDE MONO FAST, ADVAMED – POLIGLECAPRONE, M – MONO, i Glyde Mono, N – CARE MONO, RHIZOMONO, MDB MONO, GPCGLYDE MONO	Class III	Generic Name: Poliglecaprone 25 Suture renamed to Generic Name: Monofilament Poliglecaprone 25 Suture	2020-MDD/QS-133; NB2265 2020-MDD/DE-134; NB2265
Sterile Absorbable Surgical Suture 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	Class III	Generic Name: Polydioxanone Suture renamed to Generic Name: Monofilament Polydioxanone Suture	2020-MDD/QS-133; NB2265 2020-MDD/DE-134; NB2265
Sterile Non-absorbable Surgical Suture Generic Name: Braided & Coated Polyester Suture Brand name: UNIBOND, UNIBOND FAST, ADVAMED– POLYESTER, M–BOND, i Bond, N– CARE Polyester, RHIZOBOND, MDB-BOND, GPCBOND	Class IIb excluding Class IIb implantable non-WET	Generic Name: Polyester Suture renamed to Generic Name: Braided & Coated Polyester Suture	2020-MDD/QS-135; NB2265
Sterile Non-absorbable Surgical Suture Generic Name: Monofilament Polypropylene Suture Brand name: UNILENE, UNILENE FAST, ADVAMED-POLYPROPYLENE, M–LENE, i Lene, N–CARE Polypropylene, RHIZOLENE, MDB-LENE, GPCLENE	Class IIb excluding Class IIb implantable non-WET	Generic Name: Polypropylene Suture renamed to Generic Name: Monofilament Polypropylene Suture	2020-MDD/QS-135; NB2265
Sterile Non-absorbable Surgical Suture Generic Name: Monofilament Polyamide Suture	Class IIb excluding Class IIb implantable non-WET	Generic Name: Polyamide Suture renamed to Generic Name: Monofilament Polyamide Suture	2020-MDD/QS-135; NB2265

Brand name: UNILON, UNILON FAST, ADVAMED–NYLON, M–LON, i Lon, N–CARE Nylon, RHIZOLON, MDB-LON, GPCLON			
Monofilament Polypropylene Mesh Generic Name: Monofilament Polypropylene Mesh Brand name: UNILENE MESH, UNILENE MESH FAST, ADVAMED–POLYPROPYLENE MESH, M–LENE MESH, i Lene Mesh, N–Care Polypropylene Mesh, RHIZOLENE MESH, MDB-LENE MESH, GPCLENE MESH	Class IIb implantable non-WET device	Generic Name: Polypropylene Mesh renamed to Generic Name: Monofilament Polypropylene Mesh	2020-MDD/QS-136; NB2265
Sterile Non-Absorbable Surgical Suture Generic Name: Black Braided Silk Brand name: UNISIL, ADVAMED–SILK, MARFLOW–SILK, UNISIL FAST, M–SILK, ALPHA–SILK, I SILK, N-CARE SILK, RHIZOSILK	Class IIb excluding Class IIb implantable non-WET	N/A	2019-MDD/QS-073; NB2265
Sterile Non-absorbable Surgical Suture Generic Name: Monofilament Stainless Steel 316 LVM Brand name: MONOSTEEL, ADVAMED –STEEL, MARFLOW–STEEL, MONOSTEEL FAST, M–STEEL, ALPHA–STEEL, I STEEL, N-CARE STEEL, RHIZOSTEEL	Class IIb excluding Class IIb implantable non-WET	Monofilament Stainless Steel LVM 316 Grade wire renamed to Monofilament Stainless Steel 316 LVM	2019-MDD/QS-073; NB2265
Sterile Bone Wax Brand name: HAEMOWAX, ADVAMED –BONEWAX, MARFLOW –BONEWAX, M–WAX, ALPHA – WAX, I WAX, N-CARE BONEWAX, RHIZOWAX	Class IIb implantable non-WET device	N/A	2019-MDD/QS-074; NB2265

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/1/25	MIT/2024/P037	Initial issue

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 27th, 2020	May 26th, 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
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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

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, 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		
9-0	0.3		
10-0	0.2		

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Tele: +91 9108990400
E-mail: info@universalsutures.com
CIN: U33110KA2015PTC078111

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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, 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		
9-0	0.3		
10-0	0.2		

Registered Office
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Tele: +91 9108 990 400
E-mail: info@universalsutures.com
CIN: U33110KA2015PTC078111

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Bangalore - 560 013, Karnataka, INDIA
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), TAPER CUT, CUTTING, REVERSE CUTTING, BLUNT, SPATULATED, TROCAR POINT, DIAMOND POINT	½ 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		

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CIN: U33110KA2015PTC078111

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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	½ 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
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

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, Andrahalli Main Road, Acharya Industrial Complex,
Vishwaneedam Post, 560 091 Bangalore, Karnataka, India

UNISUR
LifeCare Pvt. Ltd.

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-0387/22 **Date of issuance: October 25th, 2022** **Original date of approval: November 1st, 2016**

This certificate is valid from **October 30th, 2022** to **October 29th, 2025** 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.

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

Dr. Katarína Tomín 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.