



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 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).



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

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Dr. Katarína 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

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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 ¾ 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

Bangalore

No.15/1,2,3 Andrahalli Main Road, Acharya Indl. Complex
Vishwaneedam Post, Near Anupama School
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Corporate Office

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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,	½ CIRCLE ¼ CIRCLE
3	6		
2	5		
1	4		
0	3.5		
2-0	3		
3-0	2		
4-0	1.5	BLUNT, SPATULATED, TROCER POINT, DIAMOND POINT	3/8CIRCLE 5/8 CIRCLE STRAIGHT
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 80 4166 6920

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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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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		

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