



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



*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**

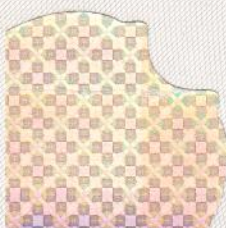
Certificate No.: M-0387/19

Date of issuance: October 31st, 2019

Original date of approval: November 1st, 2016

This certificate is valid from **October 31st, 2019** to **October 30th, 2022** 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. Katarina Tomin Šrdošová
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.



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