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.

Notified body 3EC International 2265 OVERENÁ OSOBA

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Reason: MoldSign Signature
Location: Moldova

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. 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).

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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

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

EC CERTIFICATE

No. 2020-MDD/QS-135

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

Sterile Non-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 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. 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. 310506/2020.

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 such is required. 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 fulfilment of relevant legal and other requirements by manufacturer.

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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-030/A issued on November 14th, 2019

ANNEX TO EC CERTIFICATE No. 2020-MDD/QS-135

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 Non-absorbable Surgical Suture

Generic Name	Brand Name (s)	USP Size
Polyamide Suture	UNILON, UNILON FAST, ADVAMED–NYLON, M–LON, i Lon, N–CARE Nylon, RHIZOLON, MDB-LON, GPCLON	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5
Polypropylene Suture	UNILENE, UNILENE FAST, ADVAMED–POLYPROPYLENE, M–LENE, i Lene, N–CARE Polypropylene, RHIZOLENE, MDB-LENE, GPCLENE	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5
Polyester Suture	UNIBOND, UNIBOND FAST, ADVAMED–POLYESTER, M–BOND, i Bond, N–CARE Polyester, RHIZOBOND, MDB-BOND, GPCBOND	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5

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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

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international

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

EC CERTIFICATE

No. 2020-MDD/QS-136

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

Monofilament Polypropylene Mesh

(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 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. 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. 310507/2020.

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 such is required. 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 fulfilment of relevant legal and other requirements by manufacturer.

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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-030/A issued on November 14th, 2019

ANNEX TO EC CERTIFICATE No. 2020-MDD/QS-136

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: Monofilament Polypropylene Mesh

Generic Name	Brand Name (s)	Size
Polypropylene Mesh	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	Rectangular shape: 1.2 cm x 40 cm, 1.5 cm x 45 cm, 2 cm x 20 cm, 3 cm x 6 cm, 5 cm x 10 cm, 5 cm x 20 cm, 6 cm x 11 cm, 6 cm x 12 cm, 7.5 cm x 15 cm, 7.6 cm x 15 cm, 8 cm x 12 cm, 8 cm x 15cm, 10 cm x 13 cm, 10 cm x 15 cm, 10 cm x 20 cm, 11.5 cm x 1.2 cm, 20 cm x 30 cm, 22.5 cm x 35 cm, 25 cm x 35 cm, 35.6 cm x 30 cm Square shape: 2 cm x 2 cm, 5 cm x 5 cm, 7.5 cm x 7.5 cm, 10 cm x 10 cm, 12 cm x12 cm, 15 cm x 15 cm, 20 cm x 20 cm, 25 cm x 25 cm, 30 cm x 30 cm Pre-cut shape: 4.5 cm x 10 cm, 5 cm x 5 cm, 6 cm x 11 cm, 6 cm x 13.7 cm, 7 cm x 7 cm, 7.5 cm x 12.5 cm, 8.5 cm x 15 cm, 15 cm x 15 cm Three dimensional plug flower shape: h 2.8 cm x Ø 3 cm, h 3.1 cm x Ø 3.4 cm, 2.5 cm x 3.4 cm, 3.3 cm x 3.9 cm, 3.8 cm x 5.0 cm, 4.1 cm x 4.8 cm, 4.1 cm x 5.0 cm, 5 cm x 10 cm, 6 cm x 12 cm, Ø 2.5 cm, Ø 3.25 cm, Ø 3.75 cm, Ø 4.3 cm, Ø 4.5 cm, Ø 6.4 cm, Ø 6.5 cm

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