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

UNIVERSAL SUTURES

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

Digitally signed by Iarovoi Petru
Date: 2021.09.15 18:46:47 EEST
Reason: MoldSign Signature
Location: Moldova

Dr. Katarína Tomin 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.

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

EC CERTIFICATE

No. 2019-MDD/QS-073

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll. 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 by 2007/47/EC.

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 by 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. SK-0500-19, and the Final protocol No. 310278/2019.

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 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 fulfilment of relevant legal and other requirements by manufacturer.

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

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

In Bratislava, on November 14th, 2019

ANNEX TO EC CERTIFICATE No. 2019-MDD/QS-073

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: Non-absorbable Surgical Suture

Generic Name	Brand Name (s)	USP Size
Black Braided Silk	UNISIL, ADVAMED-SILK, MARFLOW-SILK, UNISIL FAST, M-SILK, ALPHA-SILK, I SILK, N-CARE SILK, RHIZOSILK	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3
Monofilament Stainless Steel LVM 316 Grade wire	MONOSTEEL, ADVAMED-STEEL, MARFLOW-STEEL, MONOSTEEL FAST, M-STEEL, ALPHA-STEEL, I STEEL, N-CARE STEEL, RHIZOSTEEL	6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5, 6, 7

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

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

In Bratislava, on November 14th, 2019
Valid until May 26th, 2024