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-074

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 Bone Wax

Brand name: HAEMOWAX, ADVAMED-BONEWAX, MARFLOW-BONEWAX, M-WAX, ALPHA-WAX, I WAX, N-CARE BONEWAX, RHIZOWAX

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

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 BONE WAX**
Classification and Justification	:	Refer Page 2
Model/Type ref.	:	Refer Page 2
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 full fills 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 excluding section 4 of MDD 93/42/EEC as amended by 2007/47/EC.

This declaration is based on

a) Harmonizd Standards: EN ISO 15223-1:2016, EN 20417:2021, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 10993-1:2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020

b) Non-harmonized Standards: ISO/TR 20416:2020

c) Technical File. (USPL-TCF-MD-05)

AUTHORIZED REPRESENTATIVE
MEDDEVICES LIFE SCIENCE B.V.
Kraijenhoffstraat 137 A,
1018RG Amsterdam, Netherlands.
Ph. No.: +31202254558
e-mail ID: nk@meddevices.net

CE CERTIFICATE NUMBER	DATE OF ISSUE	CERTIFICATE VALIDITY
2019-MDD/QS-074	November 14th, 2019	May 26th, 2024

Manufacturer : **UNISUR LIFECARE PRIVATE LIMITED**
Name : Mr. Pavan D.C
Designation : 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
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: As per MDD 93/42/EEC as amended by 2007/47/EC, Annex IX, Title III, section 2.4 Rule 8 All implantable devices and long-term surgically invasive devices are in Class IIb.

Justification: Sterile Bone Wax is implanted on the human body for duration more than 30 days. Hence it will fall under Class IIb

Generic Name	:	Sterile Bone Wax
Brand Name	:	HAEMOWAX, ADVAMED-BONEWAX, MARFLOW-BONEWAX, M-WAX, ALPHA-WAX, I WAX, N-CARE BONEWAX, RHIZOWAX
GMDN Code	:	46930

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Bangalore
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