

EU DECLARATION OF CONFORMITY	
Product Group	Sterile Synthetic Non-Absorbable Surgical Suture
Generic Name	Monofilament Polypropylene
EMDN Code	H0102010104
Basic UDI-DI	8903837H010201010426
Brand Names	TRULENE, VETSUTURE LENE, NOÉCARE LENE, NOÉDENTAL LENE, ALPHA LENE, LINX PROLINE, LENE POLYPROPYLENE, Q-CLOSE POLYP, U-LENE, MOPYLEN, MOPYLEN CV, SURGISUT TRULENE, B- LENE, TRUVET POLYPROPYLENE, IM- LENE, EPLYENE, UNODENT POLYPROPYLENE, PROPYLECUT, N-CARE POLYPROPYLENE
Sizes	USP Sizes/EP Gauge – 10-0/0.2, 9-0/0.3, 8-0/0.4, 7-0/0.5, 6-0/0.7, 5-0/1, 4-0/1.5, 3-0/2, 2-0/3, 0/3.5, 1/4, 2/5, 3&4/6
Indented Use: Monofilament Polypropylene suture is intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological tissues.	
Registered Place of Business:	Healthium Medtech Limited No. 472 D, 13 th Cross, 4 th Phase, Peenya Industrial Area, Bangalore – 560 058, Karnataka, India. SRN No.: IN-MF-000008421
Address of the Manufacturing Unit :	Site 01: Healthium Medtech Limited No. 472 D, 13 th Cross, 4 th Phase, Peenya Industrial Area, Bangalore Karnataka-560 058. India Site 02: Healthium Medtech Limited PLOT NO: 1605, PORTIA ROAD, SRI CITY, TIRUPATI DISTRICT, ANDHRA PRADESH– 517 646, INDIA
E.U. Representative's name and address	MED DEVICES LIFESCIENCES B.V. Keizersgracht 482 1017 EG Amsterdam, The Netherlands Email:info@meddevices.net Phone: +31-202254558 SRN No.:NL-AR-000000594
Classification of the device:	Monofilament Polypropylene sutures are classified as Class III device in accordance with Rule 8 of Annex VIII of the MDR 2017/745
Notified Body's Address and Notified body number	3EC International a.s. Hranicna 18, 821 05 Bratislava, Slovak Republic. NB 2265
Certificate No.:	2022-MDR/QS-011
Document Reference No.	TD/CE/09
Applicable Standards	EN ISO 13485:2016, ISO 14971:2019, ISO 9001: 2015, EN 556-1: 2001, EN 556-2: 2015, EN 868-7:2017, EN ISO 15223-1 : 2021 , ISO 20417-2021, EN ISO 11135-2014, ISO 10993-1:2018, ISO-11607-1 : 2019, ISO-11607-2 : 2019, ISO-11737-1: 2018, ISO 11737-2: 2019, EN ISO 14155:2020, ISO 14644-1:2015, EU.PHARMACOPEIA 10th version, MEDDEV 2.7-1 rev 4, MEDDEV 2.12-1 rev 8, MEDDEV 2.12-2 rev 2.
Quality Responsibility: Healthium Medtech Limited., declares under sole responsibility for complying all the quality requirements of the product.	
Declaration: Healthium Medtech Limited, declares that Monofilament Polypropylene sutures meets the requirements of Quality as per USP specifications given in the monograph, Non-Absorbable Surgical Suture, Synthetic and also complies with MDR 2017/745 The EU declaration of conformity is issued under the sole responsibility of the manufacturer.	



Healthium Medtech Limited

(Formerly known as Healthium Medtech Private Limited)

Corporate Office: RMZ North Star, Cowrks, 12th Floor, Adjacent to RMZ Galleria Mall, Yelahanka, Bengaluru - 560 064, India

Registered Office: 472/D, 13th Cross, 4th Phase, Peenya Industrial Area, Bengaluru - 560 058, India

www.healthiummedtech.com | CIN : U03311KA1992PLC013831

Signature :	 
Name and Position	Pankaj Dawar PRRC
Date	11-Nov-2022
Place	Bangalore

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