

EU DECLARATION OF CONFORMITY	
Product Group	Sterile Synthetic Absorbable Surgical Suture
Generic Name	Monofilament Poliglecaprone 25
EMDN Code	H0101010103
Basic UDI-DI	8903837H0101010103ZG
Brand Names	MONOGLYDE, VETSUTURE PGC, NOÉCARE PGC, NOÉDENTAL PGC, PGC POLIGLECAPRONE 25, LINX MONO, Q-CLOSE MONO, FLYSORB MONO, U-MONOGLYDE, SURGISUT MONOGLYDE, B-ONOGLYDE, TRUVET POLIGLECAPRONE, IM –MONO, ECAPRONE, UNODENT PGCL, POGAL MONO, N-CARE MONOGLYDE, ALAN GLECA
Sizes	USP Sizes/EP Gauge - 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
Intended Use: Monofilament Poliglecaprone-25 suture is intended for use in general soft tissue approximation and/or ligation where an absorbable suture material is indicated. The safety and effectiveness of this suture has not been established in cardiovascular tissue, neurological tissue, microsurgery and ophthalmic surgery.	
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 Poliglecaprone-25 sutures is 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-008
Document Reference No.	TD/CE/06
Applicable Standards	EN ISO 13485:2016, ISO 14971:2019, ISO 9001: 2015, EN 556-1: 2001, EN 556-2: 2015, EN ISO 15223-1 : 2021 , EN 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, Bangalore declares under sole responsibility for complying all the quality requirements of the product.	
Declaration: Healthium Medtech Limited, declares that Monofilament Poliglecaprone-25 sutures meets the requirements of Quality as per USP specifications given in the monograph, 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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