

EU DECLARATION OF CONFORMITY	
Product Group	Sterile Synthetic Absorbable Surgical Suture
Generic Name	Monofilament Polydioxanone
EMDN Code	H0101010101
Basic UDI-DI	8903837H0101010101ZC
Brand Names	PD SYNTH, VETSUTURE PDX, NOÉCARE PDX, NOÉDENTAL PDX, LINX PDO, PDX POLYDIOXANONE, Q-CLOSE PDSYNTH, PDO RESORBA,U- PD SYNTH, SURGISUT PD SYNTH, B-PD SYNTH, TRUVET POLYDIOXANONE, IM- PDS, EXANONE, UNODENT PDO, N-CARE PD SYNTH, ALAN ANONE
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
Indented Use: Monofilament Polydioxanone suture is intended for use in general soft tissue approximation, including use in paediatric cardiovascular tissue where growth is expected to occur, and ophthalmic surgery. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable. The safety and effectiveness of Monofilament Polydioxanone suture has not been established in neurological tissue, adult cardiovascular tissue and microsurgery.	
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, 13th Cross, 4th 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 Polydioxanone 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-007
Document Reference No.	TD/CE/05
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 Polydioxanone 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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