


EC DECLARATION OF CONFORMITY	
Product Group	Sterile Polydioxanone Knotless Tissue- Closure Device
Generic Name	Sterile Polydioxanone Knotless Tissue- Closure Device
Brand Names	TRUBARB, TRUQUICK, TRULOCK, PDX BARBED, LINX BARBED, IM BARBED, RESORBA BARBED SUTURE, Q-CLOSE BARBED SUTURE.
Sizes	According to USP : 5-0, 4-0, 3-0, 2-0, 0
Indented Use: Polydioxanone Knotless Tissue-Closure Device is indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.	
Address (office and Factory) of the Manufacturer:	No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, 560 058 Bangalore, Karnataka, India Ph: +91-80-41868000 Fax: +91-80-41171056
E.U. Representative's name and address	MED DEVICES LIFESCIENCES B.V. Kraijenhoffstraat 137 A, 1018RG Amsterdam, Netherlands Email: info@meddevices.net Phone: +31-202254558
Classification of the device:	Sterile Polydioxanone Knotless Tissue- Closure Device is classified as Class III device in accordance with Rule 8 of Annex IX of the MDD 93/42/EEC.
Notified Body's Address and Notified body number	3EC International a.s. Hranicna 18, 821 05 Bratislava, Slovak Republic. NB 2265
CE Certificate & EC Design Certificate No.:	2020-MDD/QS-122 & 2020-MDD/DE-123
Document Reference No.	TF/CE/10
Applicable Standards	ISO 13485:2016, ISO 14971:2019, EN ISO 15223-1 : 2021, BS ISO 20417-2021, EN 556-1: 2001, EN 556-2: 2015, ISO 11135: 2014, ISO 10993-1:2018, EN ISO-11607-1 : 2019, EN ISO-11607-2 : 2019, EN ISO-11737-1: 2018, EN ISO 11737-2: 2019, EN ISO-14630 : 2012, ISO 14644-1:2015, EN 868-7:2017, MEDDEV 2.7-1 rev 4, MEDDEV 2.12-1 rev 8, MEDDEV 2.12-2 rev 2
Declaration: Healthium Medtech Limited Declares that Sterile Polydioxanone Knotless Tissue- Closure Device meets the requirements of Quality as per Internal specifications and also complies with the provisions of the council of Directives 93/42/EEC as amended by 2007/47/EC Directives for Medical devices.	
Signature :	
Name and Position	Pankaj Dawar Regulatory Affairs
Date	24-Aug-2021
Place	Bangalore

Healthium Medtech Limited

(Formerly known as Healthium Medtech Private Limited)

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