


EC DECLARATION OF CONFORMITY	
Product Group	Non-Absorbable Surgical Suture (Synthetic)
Generic Name	Silk Suture
Brand Names	TRUSILK
Sizes	According to USP 2 (5 Metric), 1 (4 Metric), 3&4 (6 Metric), 0 (3.5 Metric), 2-0 (3 Metric) , 3-0 (2 Metric),4-0 (1.5 Metric), 5-0 (1 Metric), 6-0 (0.7Metric), 7-0 (0.5 Metric), 8-0 (0.4 Metric),9-0 (0.3 Metric) 10-0 (0.2)Metric with or without needles
Intended Use: Trusilk 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. Ph: +91-80-41868000 Fax: +91-80-41171056
Address of the Manufacturing Unit:	Healthium Medtech Limited No. 472 D, 13 th Cross, 4 th Phase, Peenya Industrial Area, Bangalore – 560 058, 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:	Silk Suture 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 Examination No.:	2020-MDD/QS-129 & 2020-MDD/DE-130
Document Reference No.	TF/CE/02
Applicable Standards	EN ISO 13485:2016, ISO 14971:2019, EN ISO 15223-1 : 2021 , EN ISO 20417-2021, EN 556-1: 2001, EN 556-2: 2015, EN 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, ISO 14644-1:2015, EN ISO 14155-2020, MEDDEV 2.7-1 rev 4, MEDDEV 2.12-1 rev 8, MEDDEV 2.12-2 rev 2
Declaration: Healthium Medtech Limited declares that Silk Suture meets the requirements of Quality as per USP specifications given in the monograph, Non-Absorbable Surgical Suture, Synthetic, 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)

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