


EC DECLARATION OF CONFORMITY	
Product Group	Non Absorbable Surgical Suture
Model/Type	Non Absorbable Surgical Suture
UMDN Code	UMDN Code: 13910
Brand Name	TRUSILK
Generic Name	Non Absorbable Surgical Suture USP (Synthetic) Black Braided Silk
Size : According to USP 4 (6 Metric), 3 (6 Metric), 2 (5 Metric), 1 (4 Metric), 0 (3.5 Metric), 2-0 (3 Metric), 3-0 (2 Metric), 4-0 (1.5 Metric), 5-0 (1 Metric), 6-0 (0.7 Metric), 7-0 (0.5 Metric), 8-0 (0.4 Metric) with or without needles	
Quality Responsibility: Healthium Medtech Pvt Ltd. (formerly Sutures India Pvt Ltd), Bangalore declares under Sole responsibility for complying all The quality requirements of the product	
Address (office and Factory) of the Manufacturer:	Factory Address: No. 1600, R-6 West, Sri City (SEZ) Cherivi Village, Irrugulam Post, Satyavedu Mandal, Chittoor District, Andhra Pradesh-517588 Ph: +91-80-41868000 Fax: +91-80-41171056
E.U. Representative's name and address	MED DEVICES LIFESCIENCES PVT. LTD., 20-22 Wenlock Road, London, NI 7GU, U.K. Ph: +44 84552 80533
Classification of the device:	Trusilk is classified as <b>Class III device</b> in accordance with Rule 8 of Annex IX of the MDD 93/42/EEC.
Conformity Assessment Route	Annexure II including (4) (Module H) of MDD 93/42/EEC Council directives as amended by 2007/47/EC
Notified Body's Address and	<b>3EC International a.s</b> Hranicna 18, 821 05 Bratislava, Slovak Republic
Notified body number	<b>NB 2265</b>
Certificate No.:	<b>No. 2017-MDD/QS-055 /A</b> <b>Valid from:10<sup>th</sup> Nov 2017 to 09<sup>th</sup> Nov 2022</b>
Document Reference No.	<b>TF/CE/02, Rev. No: 00 Date 26.10.2017 (Sri-City)</b>
Applicable Standards	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1 : 2016 , EN 1041:2008, EN 556-1: 2001, EN 556-2: 2015, ISO 11135: 2014, ISO 10993-1:2009, ISO 10993-5: 2009, EN ISO-10993-6 :2009, ISO 10993-7: 2008, ISO 10993-10: 2010, ISO 10993-13: 2010, EN ISO-10993-11 : 2009, EN ISO-11607-1 : 2009, EN ISO-11607-2 : 2006, EN ISO-11737-1: 2006, EN ISO 11737-2: 2009, 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
<b>Declaration:</b> Healthium Medtech Pvt. Ltd. Declares that Trusilk meets the requirements of Quality as per USP specifications given in the monograph, Non Absorbable Surgical Suture, 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	<b>Malesh M</b> <b>Sr Executive RA</b>
Date	<b>23/10/2018</b>
Place	<b>Sri-City</b>

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