




Sutures
INDIA
A DIVISION OF HEALTHIUM

EC DECLARATION OF CONFORMITY	
Product Group	Non Absorbable Surgical Suture
Model/Type	Non Absorbable Surgical Suture
UMDN Code	UMDN Code: 13909
Brand Name	TRULENE
Generic Name	Non Absorbable Surgical Suture USP Monofilament Polypropylene
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:	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:	Trulene is classified as Class III device 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	3EC International a.s Hranicna 18, 821 05 Bratislava, Slovak Republic
Notified body number	NB 2265
Certificate No.:	No. 2017-MDD/QS-055 /A Valid from:10th Nov 2017 to 09th Nov 2022
Document Reference No.	TF/CE/02, Rev. No: 00 Date 26.10.2017 (Sri-City)
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
Declaration: Healthium Medtech Pvt. Ltd. Declares that Trulene 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	Malesh M. Sr. Executive RA
Date	23/10/2018
Place	Sri-City

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Factory: Plot No.1600, R-6 West, Sri City (SEZ), Cherivi Village, Irrugulam Post, Satyavedu Mandal, Chittoor District, Andhra Pradesh 517588

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CIN: U03311KA1992PTC013831