


EC DECLARATION OF CONFORMITY	
Product Group	Non Absorbable Surgical Suture
Model/Type	Non Absorbable Surgical Suture
GMDN Code	GMDN Code: 13909
Brand Name	TRULENE
Generic Name	Non Absorbable Surgical Suture USP Monofilament Polypropylene
Sizes: 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4	
Indented Use: Trulene is intended for use in soft tissue approximation and or ligation, including use in cardiovascular, ophthalmic and neurological tissues.	
Quality Responsibility: Healthium Medtech Pvt. Ltd., Bangalore declares under Sole responsibility for complying all The quality requirements of the product.	
Address (office and Factory) of the Manufacturer:	Plot No.1600, R – 6 West, Sri City (SEZ), Cherivi Village, Irrugulam Post, Satyavedu Mandal, Chittoor Dist, Andhra Pradesh – 517588, India Ph: +91-80-41868000 – 41868030
E.U. Representative's name and address	MED DEVICES LIFE SCIENCES B.V Kraijenhoffstraat 137 A, 1018RG Amsterdam, Netherlands Email: info@meddevices.net Phone: +31-202254558
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, excluding (4) (Module H) of MDD 93/42/EEC Council directives as amended by 2007/47/EC
Notified Body's Address and Notified body number	3EC International a.s Hranicna 18, 821 05 Bratislava, Slovak Republic NB 2265
Certificate No.:	2017-MDD/QS-055/B
Document Reference No.	TF/02/D
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 Regulatory Affairs
Date	27.03.2020
Place	Bangalore