


EC DECLARATION OF CONFORMITY	
Product Group	Non Absorbable Synthetic Surgical Mesh (Undyed)
Model/Type	Non Absorbable Synthetic Surgical Mesh (Undyed)
GMDN Code	GMDN Code: 60300
Brand Name	Trulene Mesh
Generic Name	Non Absorbable Synthetic Surgical Mesh (Undyed) Polypropylene Surgical Mesh
Sizes:	2.5x10, 3x6, 4x6, 4x9, 5x7.5, 6x5, 6.5x13.5, 5x9, 5x10, 6x11, 6x6, 7.5x15.2, 7.6x10, 7.2x11.7, 7.6x10, 7.6x15, 7x11, 7.5x7.5, 7.5x12.5, 8.5x11, 8x13, 8x15, 8x10, 8x12, 8x11, 8x15, 8.5x13, 10x15, 10x12, 10.5x10.5, 10x10, 10.5x11.5, 10x13, 10x15, 10x14, 10x25, 12.5x15, 12x18, 12x8, 12x12, 13.5x13.5, 13.7x6, 15x15, 15x20, 15x30, 15x19, 20x10, 20x15, 20x20, 20x25, 20x30, 26x30, 27x27, 30x30, 30x20
Indented Use:	Trulene Mesh is intended for use in the repair of Hernia, Endoscopic procedures and other facial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical results.
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:	No. 472 D, 13 th Cross, 4 th Phase, Peenya Industrial Area, Bangalore – 560 058, India Ph: +91-80-41868000 Fax: +91-80-41171056
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 Mesh is classified as Class IIb 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	3EC International a.s Hranicna 18, 821 05 Bratislava, Slovak Republic
Notified body number	NB 2265
Certificate No.:	2017-MDD/QS-051/A
Document Reference No.	TF/03A
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 Mesh meets the requirements of quality as per in-house 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	Malesh. M Regulatory Affairs
Date	27.03.2020
Place	Bangalore

