EC DECLARATION OF CONFORMITY	
Product Group	Bonewax
GMDN Code	46930
Brand Name	**Truwax**
Generic Name	Sterile bonewax
Indented Use: Truwax may be used for the control of bleeding from bone surfaces.	
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, 13th Cross, 4th 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 LIFESCIENCES B.V. Kraijenhoffstraat 137 A, 1018RG Amsterdam, Netherlands Email: info@meddevices.net Phone: +31-202254558
Classification of the device:	Truwax is classified as **Class III device** in accordance with Rule 8 of Annex IX of the MDD 93/42/EEC.
Conformity Assessment Route	Annexure ll, 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.:	**2018-MDD/QS-037/A**
Document Reference No.	**TF/CE/04**
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 Truwax meets the requirements of Quality as per the 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**