

EC DECLARATION OF CONFORMITY	
Product Group	Sterile Bone Wax
Generic Name	Sterile Bone wax
Brand Names	TRUWAX
Indented Use: Truwax may be used for the control of bleeding from bone surfaces.	
Address (office and Factory) of the Manufacturer:	No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, 560 058 Bangalore, Karnataka, India Ph: +91-80-41868000 Fax: +91-80-41171056
E.U. Representative's name and address	MED DEVICES LIFESCIENCES B.V. Keizersgracht 482 1017 EG Amsterdam, The Netherlands Email: info@meddevices.net ;Phone: +31-202254558
Classification of the device:	Sterile Bone Wax is classified as Class III device in accordance with Rule 8 of Annex IX of the MDD 93/42/EEC.
Notified Body's Address and Notified body number	3EC International a.s. Hranicna 18, 821 05 Bratislava, Slovak Republic. NB 2265
CE Certificate & EC Design Certificate No.:	2018-MDD/QS-037/B & 2018-MDD/DE-038/B
Document Reference No.	TF/CE/04
Applicable Standards	EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1 : 2021, EN ISO 20417-2021, EN 556-1: 2001, EN 556-2: 2015, ISO 10993-1:2018, ISO-11607-1 : 2019, ISO-11607-2 : 2019, ISO-11737-1: 2018, ISO 11737-2: 2019, ISO 14644-1:2015, MEDDEV 2.7-1 rev 4, MEDDEV 2.12-1 rev 8, MEDDEV 2.12-2 rev 2
Declaration: Healthium Medtech Limited declares that Sterile Bone wax 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	Pankaj Dawar Regulatory Affairs
Date	10-July-2023
Place	Bangalore

Healthium Medtech Limited

(Formerly known as iHealthium Medtech Private Limited)

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