GRAMEDICA®

Declaration of Conformity

PRODUCT IDENTIFICATION		
Product Name	**Model /Number**	**Catalog Number(s)**
HyProCure® Sinus Tarsi Stent	Size 05	HYP-05
	Size 06	HYP-06
	Size 07	HYP-07
	Size 08	HYP-08
	Size 09	HYP-09
	Size 10	HYP-10

MANUFACTURER		
Name of Company	**Address**	**Representative**
GraMedica	16137 Leone Drive Macomb, MI 48042 USA	Dr. Michael E. Graham

AUTHORIZED REPRESENTATIVE		
Name of Company	**Address**	**Telephone/Email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax Europe@emergogroup.com

REGISTRATION INFORMATION		
Notified Body and ID#	**Models**	**CE Certificate Number(s)**
SGS Belgium NV, Notified Body ID#: 1639	HyProCure Sinus Tarsi Implant System	(EC) Certificate #: US19/819943475 Start of CE-Marking: HYP Certified since: 03 June, 2006 First certified by SGS Belgium on: 16 December 2019

CONFORMITY ASSESSMENT		
Device Classification	**Route to Compliance**	**Standards Applied**
Class IIb device, according to Annex IX, of the MDD/93/42/EEC Rule 8	Annex II (excluding section 4) of the MDD/93/42/EEC and BS EN ISO13485:2016	BS EN ISO 13485:2016, BS EN 15223-1:2016, BS EN 1041:2008+A1:2013, BS EN ISO 14971:2019, BS EN ISO 11137-1:2015, BS EN ISO 11137-2:2015, ISO 11607-1:2017, ISO 11607-2:2017

GraMedica declares that the above-mentioned products meet the provision of the Council Directive MDD/93/42/EEC for Medical Devices and the Directives as transposed in the nation laws of the Member States. All supporting documentation is retained under the premises of the manufacturer.

COMPANY REPRESENTATIVE: Michael Graham, DPM

SIGNATURE: _____ **DATE:** 17 /02/2021
TITLE: President and CEO DD/MM/YYYY