GRAMEDICA®

Declaration of Conformity

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

MANUFACTURER		
Name of Company	**Address**	**Representative**
Graham Medical Technologies, L.L.C., dba **GraMedica**	16137 Leone Drive Macomb, MI 48042-4063 USA	Tony Robinson

AUTHORIZED REPRESENTATIVE		
Name of Company	**Address**	**Telephone/Email**
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem, 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	Refer to Appendix E - List of Applied Standards

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

COMPANY REPRESENTATIVE: Tony Robinson

SIGNATURE: _____

TITLE: PRESIDENT & CEO

DATE: 16/06/2023

DD/MM/YYYY

Appendix E – List of Applied Standards

The following standards have been used for guidance and/or reference for the **HyProCure Sinus Tarsi Implants/Instruments**:

Standards		Applies to	
		Implant	Instruments
EN ISO 13485:2016, EN ISO 13485:2016/A11:2021	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016)	X	X
EN ISO 14971:2012	Medical Devices – Application of risk management to medical devices (ISO 14971:2007, Corrected Version 2007-10-01)	X	X
EN ISO 14971:2019/A11:2021	Medical Devices – Application of risk management to medical devices		
IEC 62366-1:2015 (R2021) + Amd1:2020-06	Medical devices- Application of usability engineering to medical devices	X	X
EN ISO 15223-1:2021	Medical devices-Symbols to be used with information to be supplied by the manufacturer Part 1 General requirements (ISO 15223-1:2021)	X	X
EN ISO 15223-1:2016	Medical devices-Symbols to be used with information to be supplied by the manufacturer Part 1 General requirements (ISO 15223-1:2016, Corrected Version 2017-03)		
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009) EN 10093-1:2009/AC:2010	X	X
ISO 10993-1 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process		
EN 1041:2008	Information supplied by the manufacturer with medical devices	X	X
ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer	X	X
MDD 93/42/EEC (M5 Consolidated version)	Medical Device Directive	X	X
MEDDEV 2.7.1, Rev.4	Clinical Evaluation: A guide for Manufactures and Notified Bodies	X	X
EN ISO 11137-1:2015	Sterilization of health care products – Radiation **–** Part 1: Requirements for development, validation and routine control of sterilization process for medical devices (ISO 11137-1:2006/, including Amd 1:2013) EN ISO 11137-1:2015/A2:2019	X	
EN ISO 11137-1:2015/A2:2019	Sterilization of health care products – Radiation **–** Part 1: Requirements for development, validation and routine control of sterilization process for medical devices (ISO 11137-1: 2006/, including Amd 1:2013		
*** EN ISO 11137-2:2015	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	X	
EN ISO 11737-1:2006	Sterilization of medical devices – Microbiological methods – Part 1: Determination of Population of microorganisms on products (ISO 11737-1:2006) EN ISO 11737-1:2006/AC:2009		
EN ISO 11737-1:2018+A1:2021	Sterilization of medical devices – Microbiological methods – Part 1: Determination of Population of microorganisms on products.	X	
EN ISO 11737-2:2020	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	X	
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems & packaging systems (ISO 11607-1:2019)	X	
EN ISO 11607-1:2020+A11:2022	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems & packaging systems		
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing & assembly processes (ISO 11607-2:2019)	X	
EN ISO 11607-2:2020+A11:2022	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing & assembly processes		
EN ISO 14602:2011	Non-active surgical implants – Implants for osteosynthesis – Particular requirements	X	
BS EN ISO 14630:2009 (2012 same as 2009)	Non-active surgical implants – General requirements	X	
ISO 5832-3:2021	Implants for surgery-Metallic materials-Part 3: Wrought Titanium 6-aluminum 4-vanadium alloy (Ti 6-Al 4-V)	X	
EN ISO 16061:2009	Instrumentation for use in association with non-active surgical implants – General requirements (ISO 16061:2008, Corrected Version 2009-03-15)		X
ISO 16061:2021	Instrumentation for use in association with non-active surgical implants – General requirements		
*ISO 17664:2017	Processing Of health care products-Information to be provided by the medical device manufacturer for the processing of medical devices		
***ISO 17664-1:2021	Processing Of health care products-Information to be provided by the medical device		X

Appendix E – List of Applied Standards

Standards		Applies to	
		Implant	Instruments
*ISO 17664-2:2021	manufacturer for the processing of medical devices Part 1: Critical and semi-critical medical devices		
	Processing of health care products-Information to be provided by the medical device manufacturer for the processing of medical devices Part 2: Non-critical medical devices		X
* EN ISO 17665-1:2006	Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices		X
EN ISO 17665-2:2009	Sterilization of health care products – Moist Heat Part 2: Guidance on the Application of ISO 17665-1		X
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity		X
ANSI/ASQ Z1.4-2018	Sampling Procedure for Inspection by Attributes	X	X
AAMI TIR 12:2020	Designing, Testing, & Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities; a Guide for Device Manufacturers		X
AAMI ST 79:2017	Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.		X
ASTM D-4169-2022	Performance Testing of Shipping Containers & Systems	X	
ASTM F88/F88 M-2021	Standard Test Method for Seals Strength Flexible Barrier Materials	X	
ASTM F136:2013 (2021)e1	Standard Specification for Wrought Titanium – 6Aluminum -4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications	X	
ASTM F1886/F1886 M-2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	X	
ASTM F1929-2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	X	
ASTM F1980-2021	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Device Packages	X	
ASTM F2096-2011 (Reaffirmation 2019)	Standard Test Method for Detecting Leaks in Medical Packaging by Internal Pressurization	X	
ASTM F2193-2020	Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System	X	
ASTM A313/A313 M-2018	Standard Specification for Stainless Steel Spring Wire		X
ASTM A564/A564 M-2019A	Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless-Steel Bars and Shapes		X
ASTM A967/A967 M-2017	Standard Specification for Chemical Passivation Treatments for Stainless Steel Parts		X
ASTM F86-2021	Standard practice for Surface Preparation and Marking of Metallic Surgical Implants		X

* Refer to Section 2.6 Device Sterilization in the Technical File for additional information on compliance with ISO EN 17665-1 and ISO 17664.

Regrading compliance with ISO 15883: Refer to Section 2.6 Device Sterilization in the Technical File for additional information on compliance with ISO 15883. Per SGS Life Sci. test lab it is the responsibility of the user(s) to demonstrate compliance of the installed Washer/Disinfector throughout the devices working life

***BS EN ISO 11137-2:2015 is equivalent to the US standard ANSI/AAMI/ISO 11137-2:2013 (as noted on dose Audit reports)

During the annual review of the Technical File we will check for most recent list of European Norms harmonized in the Official Journal of European Communities. Searches can be conducted on European and /or other websites to determine if any new standards are applicable and to ensure that the most current revision of the standard is referenced. Updates may also occur throughout the year and will be documented per QSP 4.2-3 Document Change Control.