DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

Manufacturer:		Collagen Matrix, Inc. 15 Thornton Road Oakland, NJ 07436 USA
European Representative:		EC REP MDSS Medical Device Safety Services GmbH Schiffgraben 41, 30175 Hannover, Germany
Medical Device:	Trade Name: Part No.	SMARTGRAFT 0114.101, 0114.102, 0114.103, 0114.105, 0114.112, 0114.113
	Generic Name: *Part No.*	Porcine Anorganic Bone Mineral PMC0510, PMC1010, PMC2010, PMC4010 PMC1020, PMC2020
UMDNS Name: UMDNS Code: GMDN Code:		Bone Matrix Implants, Biological 17-756 47968
Classification - Annex IX:		Class III, Rule 8 and 17
Conformity Assessment Route:		Annex II.3 and II.4

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES - AS AMENDED BY DIRECTIVE 2007/47/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

Standards applied:	See Attached List of Standards
Notified Body:	British Standards Institution
Identification number:	CE 2797
(EC) Certificate(s):	CE 571838 and CE 631948
Start of CE-marking:	29-Jun-2020
Place, Date of Declaration:	Oakland, NJ, USA, (September 17th, 2020)
Signature:	Peggy Hansen General Manager CDM & SVP Regulatory and Clinical Affairs

15 Thornton Road, Oakland, New Jersey 07436 COLLAGEN MATRIX United States of America

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES LIST OF STANDARDS

STANDARD #	DESCRIPTION
BS EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
BS EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
BS EN 62366-1:2015	Medical Devices – Part 1: Application of Usability Engineering to Medical Devices
BS EN 1642:2011	Dentistry – Medical Devices for Dentistry – Dental Implants
BS EN ISO 22794:2009	Dentistry – Implantable materials for bone filling and augmentation in oral and maxillofacial surgery – Contents of a technical file
BS EN ISO 14630:2012	Non-active surgical implants-General requirements.
BS EN ISO 22442-1:2015	Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
BS EN ISO 22442-2:2015	Medical devices utilizing animal tissues and their derivatives. Part 2: Controls on sourcing, collection and handling
BS EN ISO 22442-3:2007	Medical devices utilizing animal tissues and their derivatives. Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents
ISO 10993-1:2018	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
BS EN ISO 10993-3:2014	Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
ISO 10993-5:2009	Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
BS EN ISO 10993-6:2016	Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation
BS EN ISO 10993-10:2013	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
BS EN ISO 10993-11:2018	Biological Evaluation of Medical Devices- Part 11: Tests for Systemic Toxicity
BS EN ISO 7405:2008 + A1:2013	Dentistry – Evaluation of Biocompatibility of Medical Devices used in Dentistry
BS EN ISO 11137-1:2015 + A2:2019	Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices.
BS EN ISO 11137-2:2015	Sterilization of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose.
BS EN ISO 11737-1:2018	Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of the Population of Microorganisms on Products.
BS EN ISO 11737-2:2009	Sterilization of Medical Devices – Microbiological Methods – Part 2: Tests of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process.
BS EN 556-1:2001	Sterilization of medical devices – requirements for medical devices to be designated "sterile" - Part 1: Requirements for terminally sterilized medical devices
BS EN ISO 11607-1:2020	Packaging for Terminally Sterilized Medical Devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems.
BS EN ISO 11607-2:2020	Packaging for Terminally Sterilized Medical Devices. Part 2: Validation Requirements for Forming, Sealing and Assembly Processes.
BS EN 1041:2008 + A1:2013	Information Supplied by the Manufacturer of Medical Devices
BS EN ISO 15223-1:2016	Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements