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, D-30175 Hannover, Germany
Medical Device:	*Trade Name:*	MIS® 4Bone RCB Resorbable Conforming Barrier Membrane Part No. 4B-C1520, 4B-C2030, 4B-C3040
	Generic Name:	Absorbable Collagen Dental Membrane CM Conformable Product Control No. CDMC1520, CDMC2030, CDMC3040
	Trade Name:	MIS® 4Bone RSB Resorbable Collagen Barrier Membrane Part No. 4B-S1520, 4B-S2030, 4B-S3040
	Generic Name:	Absorbable Collagen Dental Membrane CM I Product Control No. CM1520, CM2030, CM3040
UMDNS Name: UMDNS Code:		Periodontal Regeneration Membrane Implants, Absorbable 27-284
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 AND REGULATION (EU) 722/2012 FOR MEDICAL DEVICES MANUFACTURED UTILIZING TISSUES OF ANIMAL ORIGIN. 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 0086
(EC) Certificate(s):	CE 571838 and CE 571842
Start of CE-marking:	11-11-2013
Place, Date of Declaration:	Oakland, NJ, USA, (01-13-2014)
Signature:	Peggy Hansen Peggy Hansen, RAC V.P., Clinical, Regulatory, QA, Marketing

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

STANDARD #	DESCRIPTION
BS EN ISO 13485:2012	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
BS EN ISO 14971: 2012	Medical Devices – Application of Risk Management to Medical Devices
BS EN ISO 22442-1:2007	Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 1 Analysis and Management Risk
BS EN ISO 22442-2:2007	Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 2 Controls on Sourcing, Collection and Handling
BS EN ISO 22442-3:2007	Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 3 Validation of the Elimination and/or Inactivation of Viruses and Transmissible Agents
BS EN ISO 10993-1:2009	Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing
BS EN ISO 10993-3:2009	Biological Evaluation of Medical Devices- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
BS EN ISO 10993-4:2009	Biological Evaluation of Medical Devices- Part 4: Selection of tests for interactions with blood.
BS EN ISO 10993-5:2009	Biological Evaluation of Medical Devices- Part 5: Tests for in vitro cytotoxicity
BS EN ISO 10993-6:2009	Biological Evaluation of Medical Devices- Part 6: Test for local effects after implantation
BS EN ISO 10993-10:2009	Biological Evaluation of Medical Devices- Part 10: Test for irritation and delay type hypersensitivity
BS EN ISO 10993-11:2009	Biological Evaluation of Medical Devices- Part 11: Tests for systemic toxicity
ISO 11137-1:2006	Sterilization of health care products – Radiation - Requirements for development, validation and routine control of a sterilization process for medical devices.
ISO 11137-2: 2012	Sterilization of health care products – Radiation – Establishing the sterilization dose.
ISO 11737-1:2006	Sterilization of Medical Devices – Microbiological Method. Determination of the population of microorganisms on products.
ISO 11607-1:2009	Packaging for Terminally Sterilized Medical Devices. Requirements for materials, sterile barrier systems and packaging systems.
ISO 11607-2:2006	Packaging for Terminally Sterilized Medical Devices. Part 2: Validation requirements for forming, sealing and assembly processes
BS EN 868-5:2009	Packaging for Terminally Sterilized Medical Devices. Part 5: Sealable pouches and reels of porous materials and plastic film construction – requirements and test methods
BS EN 1041:2008	Information Supplied by the Manufacturer With Medical Devices
ISO 15223-1:2012	Symbols to be used with medical device labels. Labelling and information to be supplied – part 1. General requirements. First edition 2007-04-15