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.:	Cytoplast® RTM Collagen Resorbable Barrier Membrane RTM1520, RTM2030 and RTM3040
	Generic Name: Part No.:	Absorbable Collagen Dental Membrane CM I CM1520, CM2030, CM3040
UMDNS Name:		Periodontal Regeneration Membrane Implants, Absorbable
UMDNS Code:		27-284
GMDN Code:		58709
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 2797
(EC) Certificate(s):	CE 571838 and CE 571842
Start of CE-marking:	December 1, 2008 (represents initial date of CE-marking)
Place, Date of Declaration:	Oakland, NJ, USA (April 4th, 2019)
Signature:	Peggy Hansen Senior V.P., Quality and Regulatory 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: 2012	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 ISO 22803:2005	Dentistry. Membrane materials for guided tissue regeneration in oral and maxillofacial surgery – Contents of a technical file.
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 Souring, 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 10993-1:2009	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
BS EN ISO 10993-4:2017	Biological Evaluation of Medical Devices- Part 4: Selection of tests for interactions with blood.
ISO10993-5:2009	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: Test 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 10993-11:2009	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	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 11737-1:2006	Sterilization of Medical Devices – Microbiological Method. 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 ISO 11607-1:2009 + A1:2014	Packaging for Terminally Sterilized Medical Devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems.
BS EN ISO 11607-2:2006 + A1:2014	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 + 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.