

**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:



MDSS Medical Device Safety Services GmbH
Schiffgraben 41, D-30175 Hannover, Germany

Medical Device: *Generic Name:*

Collagen Dental Wound Dressing – Plug
Product Control No. DWDP1020

Collagen Dental Wound Dressing – Tape
Product Control No. DWD1MM-2575

Trade Name:

MIS® 4Bone Plug Resorbable Collagen Plug
Part No. 4B-P0010

MIS® 4Bone Tape Resorbable Collagen Tape
Part No. 4B-T0010

UMDNS Name and Code:

Dressings, Other, 15-216

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:

 0086

(EC) Certificate(s):

CE 571838 and CE 571845

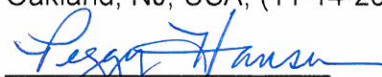
Start of CE-marking:

11-11-2013

Place, Date of Declaration:

Oakland, NJ, USA, (11-14-2013)

Signature:



Peggy Hansen, RAC

V.P., Clinical, Regulatory, QA, Marketing



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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 14630:2009	Non-active surgical implants – General Requirements
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