By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 571842**

Issued To: **Collagen Matrix, Inc.**
15 Thornton Road
Oakland
New Jersey
07436
USA

In respect of:

Absorbable Bovine Collagen Membranes for Dental Surgery

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC Annex II Section 4 and Regulation 722/2012. The design conforms to the requirements of this directive and regulation. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2011-05-24** Date: **2020-06-16** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
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Supplementary Information to CE 571842

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Absorbable Collagen Dental Membrane

Product Specific Details				
Catalogue Number	**Device Name**	**Model, Type**	**Intended purpose per IFU**	**Classification**
154	Collagen Membrane I	CM1020, 10 x 20 mm	Collagen Dental Membrane for use in oral surgical procedures	Class III
RCM-ML1520		CM1520, 15 x 20 mm		
RCM-ML2030		CM2030, 20 x 30 mm		
RCM-ML3040		CM3040, 30 x 40 mm		
N1520		CM1520, 15 x 20 mm		
N2030		CM2030, 20 x 30 mm		
N3040		CM3040, 30 x 40 mm		
RTM1520		CM1520, 15 x 20 mm		
RTM2030		CM2030, 20 x 30 mm		
RTM3040		CM3040, 30 x 40 mm		

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Product Specific Details				
Catalogue Number	**Device Name**	**Model, Type**	**Intended purpose per IFU**	**Classification**
509-6000	Collagen Membrane I	CM1520, 15 x 20 mm	Collagen Dental Membrane for use in oral surgical procedures	Class III
509-3000		CM2030, 20 x 30 mm		
509-8000		CM3040, 30 x 40 mm		
4B-S1520		CM1520, 15 x 20 mm		
4B-S2030		CM2030, 20 x 30 mm		
4B-S3040		CM3040, 30 x 40 mm		
16001520		CM1520, 15 x 20 mm		
16002030		CM2030, 20 x 30 mm		
16003040		CM3040, 30 x 40 mm		
260-509-600		CM1520, 15 x 20 mm		
260-509-300		CM2030, 20 x 30 mm		
260-509-800		CM3040, 30 x 40 mm		
32905270		CM1520, 15 x 20 mm		

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Catalogue Number	**Device Name**	**Model, Type**	**Intended purpose per IFU**	**Classification**
32905271	Collagen Membrane I	CM2030, 20 x 30 mm	Collagen Dental Membrane for use in oral surgical procedures	Class III
32905272		CM3040, 30 x 40 mm		
OUSA1EU		CM1520, 15 x 20 mm		
OUSA2EU		CM2030, 20 x 30 mm		
OUSA3EU		CM3040, 30 x 40 mm		
MBC1520		CM1520, 15 x 20 mm		
MBC2030		CM2030, 20 x 30 mm		
MBC3040		CM3040, 30 x 40 mm		

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Catalogue Number	**Device Name**	**Model, Type**	**Intended purpose per IFU**	**Classification**
509-1520	Collagen Membrane Conformable	CDMC1520, 15 x 20 mm	Collagen Dental Membrane for use in oral surgical procedures	Class III
509-2030		CDMC2030, 20 x 30 mm		
509-3040		CDMC3040, 30 x 40 mm		
4B-C1520		CDMC1520, 15 x 20 mm		
4B-C2030		CDMC2030, 20 x 30 mm		
4B-C3040		CDMC3040, 30 x 40 mm		
OUSB1EU		CDMC1520, 15 x 20 mm		
OUSB2EU		CDMC2030, 20 x 30 mm		
OUSB3EU		CDMC3040, 30 x 40 mm		

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Product Specific Details				
Catalogue Number	**Device Name**	**Model, Type**	**Intended purpose per IFU**	**Classification**
OG1520	Collagen Membrane III	CDM31520, 15 x 20 mm	Collagen Dental Membrane for use in oral surgical procedures	Class III
OG2030		CDM32030, 20 x 30 mm		
OG3040		CDM33040, 30 x 40 mm		
0103Z	Collagen Dental Membrane ZI	CMZ1520, 15 x 20 mm	Collagen Dental Membrane for use in oral surgical procedures	Class III
0105Z		CMZ2030, 20 x 30 mm		
0107Z		CMZ3040, 30 x 40 mm		
0140Z	Collagen Dental Membrane ZII	CMZM1520, 15 x 20 mm	Collagen Dental Membrane for use in oral surgical procedures	Class III
0141Z		CMZM2030, 20 x 30 mm		
0142Z		CMZM3040, 30 x 40 mm		

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Certificate History

Date	Reference Number	Action
24 May 2011	10122660	Transfer from another Notified Body, TüV; previous certificate reference G7A 10 09 42554 023.
28 August 2013	10123396	Addition of new AT sourcing location.
11 November 2013	10144193	Addition of new product trade name. Directive updated from 2003/32/EC to 722/2012. Correction to certificate history page.
	10143127	Addition of new systems CDM ZI and CDM ZII with three sizes. Scope amendment to remove 'resorbable' and replace with 'absorbable'. Addition of ETO sterilisation subcontractors.
07 May 2014	10146570	Addition of new product trade name.

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Date	Reference Number	Action
06 October 2015	10157153	Certificate renewal.
07 June 2016	10162819	Addition of trade names.
01 November 2016	10161544	DuPont Tyvek Packaging change.
13 January 2017	10162764	Addition of subcontractor Isomedix Operations, Inc., Chester, New York.
16 May 2018	8891926	Addition of Trade Names. Reformatting of product tables to include all codes.
13 February 2019	7781561	Traceable to NB 0086.
19 November 2019	3095696	Addition of Trade Names.
Current	9731637	Certificate renewal. Change of conformable variant shelf-life to 36 months. Administrative update to product table.

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