

EC Design-Examination Certificate

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

No. **CE 631948**
Issued To: **Collagen Matrix, Inc.**
15 Thornton Road
Oakland
New Jersey
07436
USA

In respect of:

Porcine Anorganic Bone Mineral

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. 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: **2015-07-09**

Date: **2020-04-02**

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.

A member of BSI Group of Companies.

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Supplementary Information to CE 631948

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
PMC0510	Porcine Anorganic Bone Mineral Cancellous Granules	PMC0510, 0.5cc (0.25-1.0mm)	Bone mineral graft for use in periodontal, oral and maxillofacial surgery.	Class III
PMC1010		PMC1010, 1.0cc (0.25-1.0mm)		
PMC2010		PMC2010, 2.0cc (0.25-1.0mm)		
PMC4010		PMC4010, 4.0cc (0.25-1.0mm)		
PMC1020		PMC1020, 1.0cc (1.0-2.0mm)		
PMC2020		PMC2020, 2.0cc (1.0-2.0mm)		
ZS050		PMC0510, 0.5cc (0.25-1.0mm)		

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ZS100		PMC1010, 1.0cc (0.25-1.0mm)		
ZS200		PMC2010, 2.0cc (0.25-1.0mm)		
ZS400		PMC4010, 4.0cc (0.25-1.0mm)		
ZL100		PMC1020, 1.0cc (1.0-2.0mm)		
ZL200		PMC2020, 2.0cc (1.0-2.0mm)		
MINXP-CAN0.5SM		PMC0510, 0.5cc (0.25-1.0mm)		
MINXP-CAN1.0SM		PMC1010, 1.0cc (0.25-1.0mm)		
MINXP-CAN2.0SM		PMC2010, 2.0cc (0.25-1.0mm)		

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MINXP-CAN4.0SM		PMC4010, 4.0cc (0.25-1.0mm)		
MINXP-CAN1.0LG		PMC1020, 1.0cc (1.0-2.0mm)		
MINXP-CAN2.0LG		PMC2020, 2.0cc (1.0-2.0mm)		
32310000		PMC0510, 0.5cc (0.25-1.0mm)		
32310001		PMC1010, 1.0cc (0.25-1.0mm)		
32310002		PMC2010, 2.0cc (0.25-1.0mm)		
32310003		PMC4010, 4.0cc (0.25-1.0mm)		
32310004		PMC1020, 1.0cc (1.0-2.0mm)		

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32310005		PMC2020, 2.0cc (1.0-2.0mm)		
ROXR05		PMC0510, 0.5cc (0.25-1.0mm)		
ROXR10		PMC1010, 1.0cc (0.25-1.0mm)		
ROXR20		PMC2010, 2.0cc (0.25-1.0mm)		
ROXR40		PMC4010, 4.0cc (0.25-1.0mm)		
ROXRLG10		PMC1020, 1.0cc (1.0-2.0mm)		
ROXRLG20		PMC2020, 2.0cc (1.0-2.0mm)		
58488		PMC0510, 0.5cc (0.25-1.0mm)		

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58489		PMC1010, 1.0cc (0.25-1.0mm)		
58490		PMC2010, 2.0cc (0.25-1.0mm)		
58491		PMC4010, 4.0cc (0.25-1.0mm)		
58492		PMC1020, 1.0cc (1.0-2.0mm)		
58493		PMC2020, 2.0cc (1.0-2.0mm)		
LBNB0510		PMC0510, 0.5cc (0.25-1.0mm)		
LBNB1010		PMC1010, 1.0cc (0.25-1.0mm)		
LBNB2010		PMC2010, 2.0cc (0.25-1.0mm)		

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LBNB4010		PMC4010, 4.0cc (0.25-1.0mm)		
LBNB1020		PMC1020, 1.0cc (1.0-2.0mm)		
LBNB2020		PMC2020, 2.0cc (1.0-2.0mm)		
XBS050		PMC0510, 0.5cc (0.25-1.0mm)		
XBS100		PMC1010, 1.0cc (0.25-1.0mm)		
XBS200		PMC2010, 2.0cc (0.25-1.0mm)		
XBS400		PMC4010, 4.0cc (0.25-1.0mm)		
XBL100		PMC1020, 1.0cc (1.0-2.0mm)		

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XBL200		PMC2020, 2.0cc (1.0-2.0mm)		
PMCS025	Porcine Anorganic Bone Mineral in Delivery Syringe	PMCS025, 0.25cc (0.25-1.0mm)	Bone mineral graft for use in periodontal, oral and maxillofacial surgery.	Class III
PMCS05		PMCS05, 0.5cc (0.25-1.0mm)		
PMCS10		PMCS10, 1.0cc (0.25-1.0mm)		
ZY025		PMCS025, 0.25cc (0.25-1.0mm)		
ZY050		PMCS05, 0.5cc (0.25-1.0mm)		
ZY100		PMCS10, 1.0cc (0.25-1.0mm)		

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MINXP-SYR0.25		PMCS025, 0.25cc (0.25-1.0mm)		
MINXP-SYR0.5		PMCS05, 0.5cc (0.25-1.0mm)		
MINXP-SYR1.0		PMCS10, 1.0cc (0.25-1.0mm)		
32310006		PMCS025, 0.25cc (0.25-1.0mm)		
32310007		PMCS05, 0.5cc (0.25-1.0mm)		
32310008		PMCS10, 1.0cc (0.25-1.0mm)		
ROXRS025		PMCS025, 0.25cc (0.25-1.0mm)		

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ROXRS05		PMCS05, 0.5cc (0.25-1.0mm)		
58494		PMCS025, 0.25cc (0.25-1.0mm)		
58495		PMCS05, 0.5cc (0.25-1.0mm)		
LBNBS025		PMCS025, 0.25cc (0.25-1.0mm)		
LBNBS050		PMCS05, 0.5cc (0.25-1.0mm)		

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Certificate History

Date	Reference Number	Action
09 July 2015	10154086	First issue.
14 June 2016	10157056 10162825	Addition of syringe delivery devices PMCS025, PMCS05, and PMCS10. Addition of new product trade names.
01 November 2016	10161544	DuPont Tyvek Packaging change.
13 January 2017	10162764	Addition of subcontractor Isomedix Operations, Inc., Chester, New York.
20 April 2017	10168274	Addition of Collagen Matrix, Allendale, New Jersey for manufacture.
21 December 2017	8792501 8844677	Addition of new product trade names. IFU update to include post-operative care procedure.
13 February 2019	7781561	Traceable to NB 0086.
19 November 2019	3095856	Addition of Trade Names. Reformatting of product tables.
Current	9666755	Certificate Renewal. Change to the processing of the raw material and upscale of the manufacturing process.

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