

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Collagen Matrix, Inc.
15 Thornton Road
Oakland
New Jersey
07436
USA

Facility ID Number: F000134

Holds Certificate No: **MDSAP 689907**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021


Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development, manufacture and distribution of non-active orthopaedic, soft-tissue, dental and neurological implants; and collagen-based, bone mineral-based and synthetic-based medical devices for tissue repair and regeneration.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-04-29

Effective Date: 2026-03-17

Expiry Date: 2029-03-16



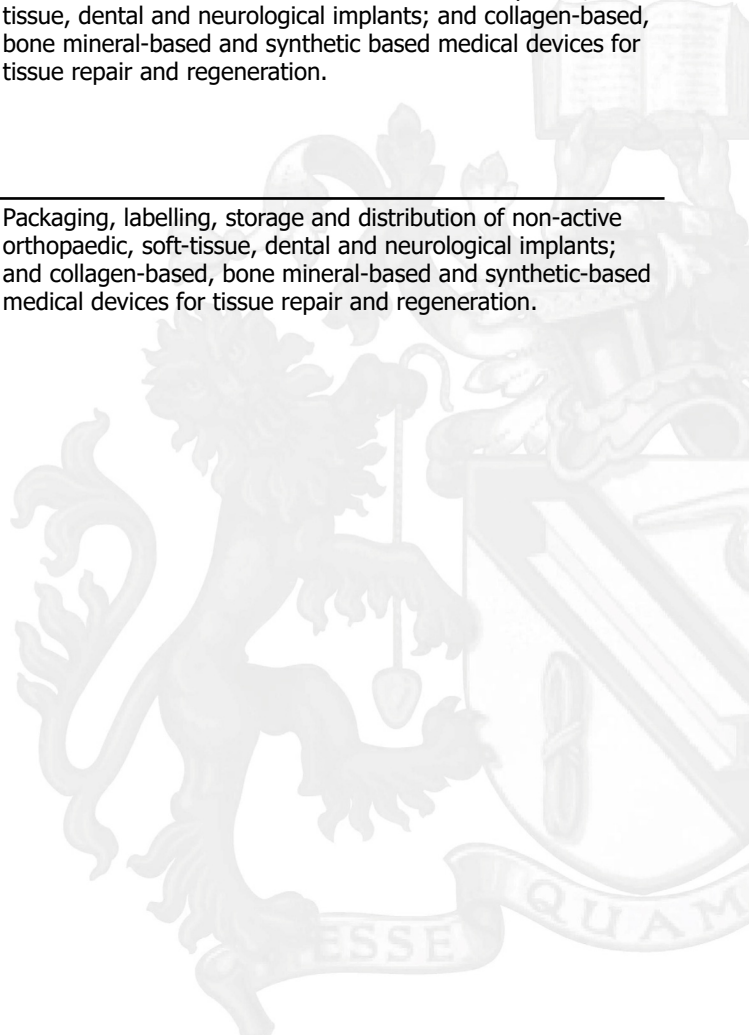
BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 689907**

| Location | Registered Activities |
|---|---|
| Collagen Matrix, Inc. 15 Thornton Road Oakland New Jersey 07436 USA Facility ID Number: F000134 | Design, development, and manufacture of non-active orthopaedic, soft-tissue, dental and neurological implants; and collagen-based, bone mineral-based and synthetic-based medical devices for tissue repair and regeneration. |
| Collagen Matrix, Inc. 110 Commerce Drive Allendale New Jersey 07401 USA Facility ID Number: F007353 | Manufacture and distribution of non-active orthopaedic, soft-tissue, dental and neurological implants; and collagen-based, bone mineral-based and synthetic based medical devices for tissue repair and regeneration. |
| Collagen Matrix, Inc. 10 Industrial Avenue, Suite 4 Mahwah New Jersey 07430 USA Facility ID Number: F007353 | Packaging, labelling, storage and distribution of non-active orthopaedic, soft-tissue, dental and neurological implants; and collagen-based, bone mineral-based and synthetic-based medical devices for tissue repair and regeneration. |



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

America Headquarters: BSI Group America Inc. 1950 Opportunity Way, Suite 900, Reston, VA 20190.
A Member of the BSI Group of Companies.