



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Zest Anchors, LLC also DBA Zest Dental Solutions and Danville Materials 2875 Loker Avenue East Carlsbad California 92010 USA

Facility ID Number: F000494

Holds Certificate No:

MDSAP 694712

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-04-30

Effective Date: 2022-04-19

Expiry Date: 2024-07-13

Page: 1 of 3





BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit."

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

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA A Member of the BSI Group of Companies.

Certificate No: MDSAP 694712

Registered Scope:

The design, manufacture, packaging and distribution of dental endosseous implants, implant anchors, root, bar attachments and accessories, attachment processing material, composite restorative and dental adhesive materials, dental impression materials, and dental air abrasion systems.

The control of manufacture and packaging of dental endoscope sterile sheaths.

The design of dental endoscope sterile sheaths.



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Page: 2 of 3

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Location

Zest Anchors, LLC Also Trading As Zest Anchors, Inc. and Zest Anchors 2230 Enterprise Street Escondido California 92029 USA Facility ID Number: F000494

Zest Anchors, LLC also DBA Zest Dental Solutions and Danville Materials 2875 Loker Avenue East Carlsbad California 92010 USA Facility ID Number: F000494

Danville Materials Research Center 4020 E. Leaverton Ct. Anaheim California 92807 USA Facility ID Number: F001850 **Registered Activities**

Manufacturing, cleaning and inspection of dental implant systems.

The design, manufacture, packaging and distribution of dental endosseous implants, implant anchors, root, bar attachments and accessories, attachment processing material, composite restorative and dental adhesive materials, dental impression materials, and dental air abrasion systems.

The control of manufacture and packaging of dental endoscope sterile sheaths.

The design of dental endoscope sterile sheaths.

Manufacturing, packaging and distribution of composite restorative and dental adhesive materials, dental impression materials.

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Page: 3 of 3

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