



## 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

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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-04-30 Effective Date: 2024-07-14 Expiry Date: 2027-07-13

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MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit."

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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## Location Registered Activities

Zest Anchors, LLC Also Trading As Zest Anchors, Inc.

and Zest Anchors 2230 Enterprise Street Escondido California

California 92029 USA

Facility ID Number: F006039

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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