

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: The Argen Corporation
5855 Oberlin Drive
San Diego
California
92121
USA

Facility ID Number: F001460

Holds Certificate No: **MDSAP 697827**

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 alloys, ceramics, abutments and clear aligners used in fixed and removable dental prosthetics.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-04-09

Effective Date: 2023-11-16

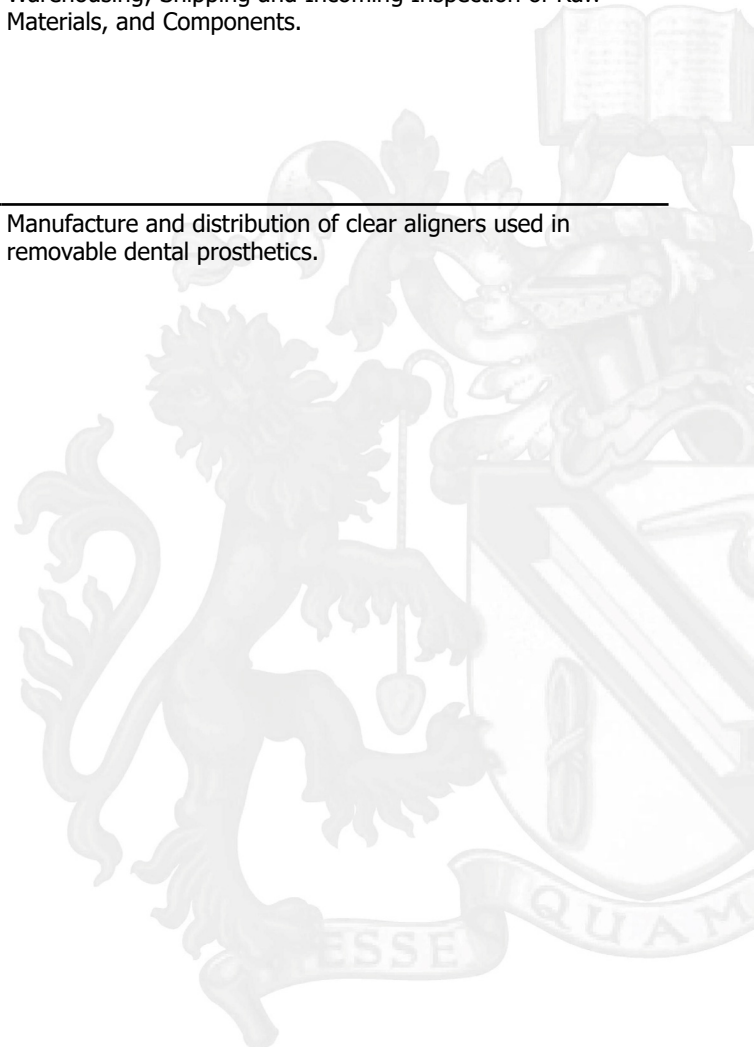
Expiry Date: 2025-12-21



BSI Group America Inc. is an MDSAP recognised auditing organization

Certificate No: **MDSAP 697827**

Location	Registered Activities
The Argen Corporation 5855 Oberlin Drive San Diego California 92121 USA Facility ID Number: F001460	Design, development, manufacture and distribution of alloys, ceramics, abutments and clear aligners used in fixed and removable dental prosthetics.
The Argen Corporation 8525 Miralani Drive San Diego California 92126 USA Facility ID Number: F001460	Warehousing; Shipping and Incoming Inspection of Raw Materials, and Components.
The Argen Corporation 8515 Miralani Drive San Diego California 92126 USA Facility ID Number: F001460	Manufacture and distribution of clear aligners used in removable dental prosthetics.



Original Registration Date: 2020-04-09

Effective Date: 2023-11-16

Expiry Date: 2025-12-21

Page: 2 of 2

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.

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