

# 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

DUNS Number: 10-309-5543

Holds Certificate No:

**MDSAP 697827**

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, Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 - Production 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

Design, development, manufacture of alloys and ceramics used in fixed and removable dental prosthetics.

For and on behalf of BSI:

\_\_\_\_\_  
Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-04-09

Effective Date: 2020-04-09

Expiry Date: 2022-12-21



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 697827**

Location	Registered Activities
The Argen Corporation 5855 Oberlin Drive San Diego California 92121 USA DUNS Number: 10-309-5543	Design, development, manufacture of alloys and ceramics used in fixed and removable dental prosthetics.
The Argen Corporation 6837 Nancy Ridge Drive San Diego California 92121 USA	Receiving of zirconia and alloys and Distribution of alloys.
THE ARGEN CORPORATION 8515 Miralani Drive San Diego California 92126 USA	Design, development, manufacture of alloys and ceramics used in fixed and removable dental prosthetics.



Original Registration Date: 2020-04-09

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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](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://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.