

# 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

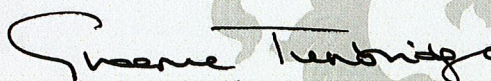
**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**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

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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 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

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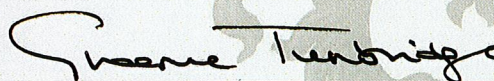
Holds Certificate Number:

FM 703167

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

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: 2008-10-20

Latest Revision Date: 2022-12-14

Effective Date: 2022-12-22

Expiry Date: 2025-12-21

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Certificate No: FM 703167

Location	Registered Activities
The Argen Corporation 5855 Oberlin Drive San Diego California 92121 USA	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	Warehousing; Shipping and Incoming Inspection of Raw Materials, and Components.
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Original Registration Date: 2008-10-20

Latest Revision Date: 2022-12-14

Effective Date: 2022-12-22

Expiry Date: 2025-12-21

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Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands  
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.  
Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.