

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Avalign Technologies, Inc.  
8727 Clinton Park Dr.  
Fort Wayne  
Indiana  
46825  
USA

Holds Certificate No:

**FM 657490**

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

Design & development, manufacturing of surgical instruments.



For and on behalf of BSI:

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

Original Registration Date: 2017-03-01

Latest Revision Date: 2020-09-22

Effective Date: 2020-02-29

Expiry Date: 2023-02-28

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Certificate No: **FM 657490**

Location

Avalign Technologies, Inc.  
8727 Clinton Park Dr.  
Fort Wayne  
Indiana  
46825  
USA

Registered Activities

Design & development, manufacturing of surgical instruments.

Avalign Integrated, LLC  
dba Avalign Integrated Medical Solutions  
7124 Industrial Park Blvd  
Mentor  
Ohio  
44060  
USA

Contract manufacturer of non-sterile medical devices.



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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.