

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Avalign-Instruments & Implants  
8727 Clinton Park Drive  
Ft. Wayne  
Indiana  
46825  
USA

Holds Certificate No:

**FM 509952**

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

Contract manufacturer of Orthopedic Instruments and Implants.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2006-12-08

Latest Revision Date: 2018-11-29

Effective Date: 2018-12-08

Expiry Date: 2021-12-07

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Certificate No: **FM 509952**

Location

Avalign-Instruments & Implants  
8727 Clinton Park Drive  
Ft. Wayne  
Indiana  
46825  
USA

Registered Activities

Contract manufacturer of Orthopedic Instruments and Implants.

Avalign-Instruments & Implants  
8414 Clinton Park Dr.  
Ft. Wayne  
Indiana  
46825  
USA

Contract manufacturer of Orthopedic Instruments and Implants.



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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.