

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

**NGI Instruments, Inc.**  
**dba Avalign Cutting Instruments**  
4643 North State Road 15  
Warsaw  
Indiana  
46582  
USA

Holds Certificate Number:

FM 541948

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

The contract manufacturer of orthopedic drills, taps and reamers.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2009-02-24

Latest Revision Date: 2022-09-15

Effective Date: 2021-02-24

Expiry Date: 2024-02-23

Page: 1 of 1



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