

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

NGInstruments, 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: 2023-12-06

Effective Date: 2024-02-24

Expiry Date: 2027-02-23

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