

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

Facility ID Number: F005123

Holds Certificate No:

MDSAP 733995

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

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

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, Development, and Manufacture of instruments used for orthopedic, spine, sports medicine, and general surgical procedures.

Design, Development, and Manufacture of sterile intervertebral body fusion devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-10-20

Effective Date: 2026-03-01

Expiry Date: 2029-02-28



BSI Group America Inc. is an MDSAP recognised auditing organization

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