

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 Number:

FM 657490

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

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: 2017-03-01

Latest Revision Date: 2026-02-19

Effective Date: 2026-03-01

Expiry Date: 2029-02-28

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