



## Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Avalign Additive / Slice Manufacturing Studios 1810 Triplett Blvd. Akron Ohio 44306 USA

Holds Certificate No:

FM 653080

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

Contract Manufacturing of sterile and non-sterile medical devices and components including ceramic, plastic, and metal products. Products may be implantable or non-implantable.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2016-08-16 Latest Revision Date: 2022-06-28

bsi.



Effective Date: 2022-08-16 Expiry Date: 2025-08-15

Page: 1 of 1

...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at 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.