



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Advantis Medical, Inc.
dba Avalign Delivery Systems Division
2121 Southtech Drive
Suite 600
Greenwood
Indiana
46143
USA

Holds Certificate No:

FM 576122

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

Manufacture of cassettes and medical cases.

Previous certificate expired on 2019-02-28 (ISO 13485:2003 expiration)
Transition audit ended 2019-01-05

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2012-02-03

Latest Revision Date: 2019-03-04

Effective Date: 2017-01-05

Expiry Date: 2020-01-04

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