

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Red Star Contract Manufacturing, Inc.  
1560 North State Road 5  
Larwill  
Indiana  
46764  
USA

Holds Certificate No:

**FM 592497**

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

Contract manufacturing including injection molding, assembly and packaging of non-sterile biopsy needles and instrument systems.

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2013-01-08

Latest Revision Date: 2019-01-04

Effective Date: 2019-01-08

Expiry Date: 2022-01-07

Page: 1 of 1



...making excellence a habit.™