

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 of non-sterile biopsy needles, molded orthopedic and spine instruments, machined orthopedic and spine implants and instruments, instrument assemblies, sterile packaging, non-sterile packaging, and distribution of sterile devices and kits.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2013-01-08

Latest Revision Date: 2021-12-28

Effective Date: 2022-01-08

Expiry Date: 2025-01-07

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