

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Lincotek Medical, LLC
867 West 400 North
Logan
Utah
84321
USA

Holds Certificate Number:

FM 506694

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

The manufacture of sterile and non-sterile implants and instrumentation for the medical device industry. Manufacture and distribution of the suture passer and suture passer flexible needle for the area of orthopedic surgery.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2006-12-18

Latest Revision Date: 2022-09-15

Effective Date: 2021-09-25

Expiry Date: 2024-09-24

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