

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Lincotek Medical, LLC
811 Northwoods Blvd
Vandalia
Ohio
45377
USA

Holds Certificate Number:

FM 590101

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 needles, implants, and instrumentation, including precision machining of metals and plastics.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2012-08-20

Latest Revision Date: 2024-08-22

Effective Date: 2024-10-04

Expiry Date: 2027-10-03

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