

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Key Surgical LLC
8101 Wallace Road
Eden Prairie
Minnesota
55344
USA

Holds Certificate Number:

MD 666821

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

Manufacture and distribution of devices for surgical instrument identification, cleaning and protection. Manufacture of sterile electro-cautery lubricating device, sterile vascular loops, sterile vascular booties for use with sutures, sterile and non-sterile K-wire and pin covers, sterile cautery tip cleaners, sterile surgical skin markers and sterile and non-sterile silicone clamp covers for jaws of surgical clamps.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-03-21

Latest Revision Date: 2020-05-05

Effective Date: 2020-05-12

Expiry Date: 2023-05-11

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