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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-03-21 Effective Date: 2023-05-12 Latest Revision Date: 2023-05-09 Expiry Date: 2026-05-11





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