

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

K2M, Inc.
600 Hope Parkway SE
Leesburg
Virginia
20175
USA

Holds Certificate Number: FM 522556

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

Design, development, manufacture and distribution of sterile and non-sterile occipital, cervical, thoracic and lumbar plating systems, pedicle screw and vertebral spacers for spinal fusion, dynamic stabilization system, sterile packed instruments (including needle based products), sterile minimally invasive retractor system and associated implant trials.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2007-11-26

Latest Revision Date: 2024-05-29

Effective Date: 2024-07-19

Expiry Date: 2027-07-18

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