

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Integra LifeSciences Corporation

4900 Charlemar Drive
Building A
Cincinnati
Ohio
45227
USA

Holds Certificate Number:

FM 702220

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

Design, manufacturing, servicing and distribution of reusable and sterile disposable skull pins, neurosurgical headrests, skull clamps, self-retaining retractor systems, table mounted retractor systems, operating table accessories, skin graft instruments and surgical equipment. Distribution of operating table covers, BRS retractor system. Manufacturing and distribution of Stereotactic instrumentation and software, ultrasonic surgical systems and accessories, electrodes and accessories for tissue ablation. Contract manufacturing, servicing, and distribution of bone fixation plates and screws, drill bits and burr hole covers, and passive orthopedic implants.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2009-04-07

Latest Revision Date: 2022-09-15

Effective Date: 2022-04-19

Expiry Date: 2025-04-18



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