

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Smith & Nephew, Inc.
1450 Brooks Road
Memphis
Tennessee
38116
USA

Holds Certificate No:

FM 703477

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 non-active Orthopaedic implants (Hip, Knee, Shoulder, Wrist and Trauma Products) and associated instruments, bone cement and accessories, irrigation devices, electrically powered surgical instruments, image-guided surgical systems, hydroxyapatite coating system and additive manufacturing (3-D Printing).

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2006-12-13

Latest Revision Date: 2022-04-06

Effective Date: 2022-04-09

Expiry Date: 2025-04-08

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...making excellence a habit.™

Certificate No: **FM 703477**

Location	Registered Activities
Smith & Nephew, Inc. 1450 Brooks Road Memphis Tennessee 38116 USA	Manufacture of non-active Orthopaedic implants (Hip, Knee, Shoulder, Wrist and Trauma products) and associated instruments, hydroxyapatite coating system and additive manufacturing (3-D printing).
Smith & Nephew 3510 Winchester Rd. Memphis Tennessee 38118 USA	Receiving and storage of packaging components used in sterile packaging operations. Non-sterile repackaging of Non-active Orthopaedic implants (Hip, Knee, Shoulder, Wrist and Trauma products) and associated instruments.
Smith & Nephew, Inc. 6409 East Holmes Road Memphis Tennessee 38141 USA	Manufacture of Non-active, Sterile Orthopaedic Implants (Hip and Knee Products).
Smith & Nephew, Inc. 3303 East Holmes Road Memphis Tennessee 38118 USA	<p>Distribution of non-active Orthopaedic implants (Hip, Knee, Shoulder, Wrist and Trauma products) and associated instruments, bone cement and accessories, irrigation devices, electrically powered surgical instruments and image guided surgical systems.</p> <p>Loaners inspection and distribution for non-active Orthopaedic implants (Hip, Knee, Shoulder, Wrist and Trauma products) and associated instruments.</p>
Smith & Nephew, Inc. 7135 Goodlett Farms Pkwy Cordova Tennessee 38016 USA	Design, Development of Non-active Sterile and non-sterile Orthopaedic Implants (Hip, Knee, Shoulder, Wrist and Trauma Products) and Associated Sterile and Non-sterile Instruments, Bone Cement and Accessories, Irrigation Devices, Electrically Powered Surgical Instruments, and Image-Guided Surgical Systems.

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This certificate remains the property of BSI and shall be returned immediately upon request.

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To be read in conjunction with the scope above or the attached appendix.