

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

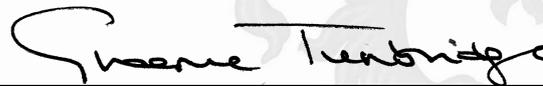
Holds Certificate No:

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	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. Loaners inspection and distribution for non-active Orthopaedic implants (Hip, Knee, Shoulder, Wrist and Trauma products) and associated instruments.
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.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.