

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Zimmer Inc.
1800 W. Center Street
Warsaw
Indiana
46580
USA

Facility ID Number: F000500

Holds Certificate No:

MDSAP 668016

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, Manufacture and Distribution of Orthopaedic Implants, Fracture Management Devices and related Instrumentation: Total hip prostheses, hip endoprostheses, total knee prostheses, total shoulder prostheses, other total joints, fracture fixation devices, bone sampling devices and bone sampling Instrumentation, bone cement, orthopaedic instruments in combination with active devices and trial prostheses.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-12-14

Effective Date: 2021-09-17

Expiry Date: 2024-08-21



BSI Group America Inc. is an MDSAP authorized auditing organization

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Location	Registered Activities
Zimmer, Inc. 1800 W. Center Street Warsaw Indiana 46580 USA Facility ID Number: F000500	Management for the site; Quality Assurance, Regulatory Assurance, Human Resources, IT, Design, Development, Research, Testing Laboratories, Engineering, Maintenance, Metrology, Receiving. Processes include Machining, Assembly, Final Cleaning, Packaging, Testing, Labeling.
Zimmer, Inc. 1777 W. Center Street Warsaw Indiana 46580 USA Facility ID Number: F000500	Machining, Assembly, Packaging, Testing This building includes distribution/warehouse, and Packaging Development testing laboratory, Customer Service, Complaint Handling, Regulatory Affairs, Clinical.
Zimmer, Inc. 1612 Armstrong Rd. Warsaw Indiana 46580 USA Facility ID Number: F000500	Processes include Machining, Assembly, Final Cleaning, Packaging, Testing, Labeling.
Zimmer, Inc. 1535 W. Center Street Warsaw Indiana 46580 USA Facility ID Number: F000500	Processes include Foundry, Machining, Assembly, Final Cleaning, Packaging, Testing, Labeling.

Original Registration Date: 2018-12-14

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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](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory

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