

bsi.



By Royal Charter

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

Zimmer GmbH  
Sulzerallee 8  
Winterthur  
8404  
Switzerland



GIÁM ĐỐC  
*Nguyễn Quý Hải*

DUNS Number: 48-813-3448

Holds certificate No:

**MDSAP 688489**

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 [if design controls are part of the certification]; 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

The design, development, manufacturing, sales, distribution and servicing of orthopaedic implants: endoprosthetic, osteosynthesis, spine, surgical instruments and products for sports medicine. Distribution of biological products and in-vitro diagnostic devices.

For and on behalf of BSI:

*Pitanga*  
Carlos Pitanga, Chief Operating Officer Assurance - Americas

Original Registration Date: 2018-08-17

Effective Date: 2018-08-17

Expiry date: 2021-08-16

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**MDSAP**  
MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP authorized auditing organization

This certificate remains the property of BSI and shall be returned immediately upon request.  
To be read in conjunction with the scope above or the attached appendix.

Managed by: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.