

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Medical Device and Implants LLC
1824 Colonial Village Lane
Lancaster
Pennsylvania
17601
USA

Facility ID Number: F007721

Holds Certificate No:

MDSAP 815988

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

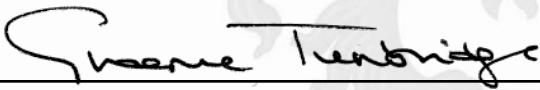
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The contract manufacture of metal and plastic orthopedic implants and instrumentation.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-01-21

Effective Date: 2025-01-21

Expiry Date: 2028-01-18



MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 2

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Certificate No: **MDSAP 815988**

Location	Registered Activities
Medical Device and Implants LLC 1824 Colonial Village Lane Lancaster Pennsylvania 17601 USA Facility ID Number: F007721	The contract manufacture of metal and plastic orthopedic implants and instrumentation.
Medical Device and Implants LLC 1813 Colonial Village Lane Lancaster Pennsylvania 17601 USA Facility ID Number: F007721	The contract manufacture of metal and plastic orthopedic implants and instrumentation.

Original Registration Date: 2025-01-21 Effective Date: 2025-01-21 Expiry Date: 2028-01-18

Page: 2 of 2

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.

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