



## Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Ortho Arch Company, Inc. 1107 Tower Road Schaumburg Illinois 60173 USA

Facility ID Number: F006184

Holds Certificate No:

**MDSAP 772026** 

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

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: 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

Manufacture and distribution of non-sterile orthodontic devices and instruments.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-04-20

Effective Date: 2023-04-20

Expiry Date: 2026-01-04

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...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. 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.