

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

American Orthodontics Corporation  
3524 Washington Avenue  
Sheboygan  
Wisconsin  
53081  
USA

Facility ID Number: F006793

Holds Certificate No:

**MDSAP 790975**

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

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-05-30

Effective Date: 2023-05-30

Expiry Date: 2024-09-04



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 790975**

## Registered Scope:

The design and manufacture of orthodontic bands, orthodontic buccal tubes, ceramic brackets, composite (plastic) brackets, bondable devices, elastomeric products, fixed and functional products, lingual attachments, orthodontic wire products, orthodontic wire-springs, wire attachments, orthodontic treatment supplies, instruments, stainless steel brackets, orthodontic appliance fabrication materials and orthodontic stops and hooks.

The purchase for resale of orthodontic wire products, elastomeric products, orthodontic instruments, orthodontic supplies and bonding agents.



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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](https://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.