

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

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2023-05-30

Effective Date: 2024-10-25

Expiry Date: 2027-09-04



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 distribution of orthodontic wire products, elastomeric products, orthodontic instruments, orthodontic supplies and bonding agents.



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Page: 2 of 3

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.

Certificate No: **MDSAP 790975**

Location

American Orthodontics Corporation
3524 Washington Avenue
Sheboygan
Wisconsin
53081
USA
Facility ID Number: F006793

Registered Activities

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 wiresprings, wire attachments, orthodontic treatment supplies, instruments, stainless steel brackets, orthodontic appliance fabrication materials and orthodontic stops and hooks.

The distribution of orthodontic wire products, elastomeric products, orthodontic instruments, orthodontic supplies and bonding agents.

American Orthodontics Corporation
3265 Northwoods Road
Saukville
Wisconsin
53080
USA
Facility ID Number: F006793

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 spring, wire attachments, orthodontic treatment supplies, instruments, stainless steel brackets, orthodontic appliance fabrication materials and orthodontic stops and hooks.



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