CERTIFICATE OF REGISTRATION

American Orthodontics Corp

3524 Washington Avenue
Sheboygan, Wisconsin 53081 UNITED STATES

Facility ID: F001384

UL Medical Regulatory Services of UL LLC®(UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

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.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Authorized by

Paul Hilgeman
Director & Global Industry Leader, Medical
CMIT – Medical Regulatory

Check Certificate Status:
here

File Number	A4041	Cycle Start Date	September 5, 2021
Certificate Number	1728.220905	Effective Date	September 5, 2022
Initial Issue Date	September 5, 2018	Expiry Date	September 4, 2024

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC.
Certificates may be verified by visiting the Online Certifications Directory on UL.com.

UL REGISTERED FIRM

UL Medical and Regulatory Services UL, LLC is an MDSAP Recognized Auditing Organization

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

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Additional Regulatory 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 (,as applicable)

United States:
- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)

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