



# CERTIFICATE OF REGISTRATION

## American Orthodontics Corp

3524 Washington Avenue  
Sheboygan, Wisconsin 53081 UNITED STATES

REPs 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, Elastomeric Products, Fixed & Functional Products, Lingual Attachments, Orthodontic Head Gear, Orthodontic Wire Products, Orthodontic Wire-Springs, Orthodontic Treatment Supplies, Stainless Steel Brackets, Orthodontic Appliance Fabrication Materials and Orthodontic Stops & Hooks.

The purchase for resale of Orthodontic Wire Products, Elastomeric Products, Orthodontic Instruments, Orthodontic Supplies, and Adhesives

Authorized by

**Deborah Jennings-Conner**  
Global Regulatory Director  
UL Life and Health Sciences  
UL LLC



Check Certificate  
Status: [here](#)



|                    |                   |                  |                    |
|--------------------|-------------------|------------------|--------------------|
| File Number        | A4041             | Cycle Start Date | September 5, 2018  |
| Certificate Number | 1728.200929       | Effective Date   | September 29, 2020 |
| Initial Issue Date | September 5, 2018 | Expiry Date      | September 4, 2021  |

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 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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