



# CERTIFICATE OF REGISTRATION

## TP Orthodontics, Inc.

100 Center Plaza  
La Porte, Indiana 46350-9672 UNITED STATES

Facility ID: F004329

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, manufacture and distribution of non sterile orthodontic brackets, wires, ligatures, adhesives, elastomers and related accessories.

Authorized by



**Paul Hilgeman**

**Director & Global Industry Leader, Medical  
CMIT – Medical Regulatory**

Check Certificate Status:

[here](#)

File Number	A28804	Cycle Start Date	October 31, 2022
Certificate Number	2756.221031	Effective Date	October 31, 2022
Initial Issue Date	October 31, 2019	Expiry Date	October 30, 2025

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. 665/2022  
- RDC ANVISA n. 551/2021  
- 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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