Certificate of Registration

Certificate number
2756.251031

File number
A28804

Initial issue date
2019-10-31

Cycle start date
2025-10-31

Effective date
2025-10-31

Expiry date
2028-10-30

TP Orthodontics, Inc.

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

Facility ID: F004329

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016
EN ISO 13485:2016/A11:2021

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

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

Certificate with Addendum(s) totals 3 pages.

Authorized by:

Paul Daysh
Operations manager – Medical Regulatory

Check certificate status: here

This quality system registration is included in UL's Product iQ directory and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown. By issuance of this certificate, the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferrable and remains the property of UL Solutions.

UL LLC, UL Solutions medical regulatory services is an MDSAP Recognized Auditing Organization

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

Addendum 1

Site	Company Name	Location	Performing
1-1	TP Orthodontics, Inc.	100 Center Plaza La Porte Indiana 46350-9672 UNITED STATES Facility ID: **F004329**	Design, manufacture, distribution.

Additional Regulatory Requirements

TP Orthodontics, Inc.
100 Center Plaza
La Porte, Indiana 46350-9672 UNITED STATES

Facility ID: F004329

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)