



# CERTIFICATE

**EC Certificate No. 1434-MDD-385/2021**

**Production Quality Assurance**

**Directive 93/42/EEC concerning medical devices**

Polish Centre for Testing and Certification certifies  
that the quality assurance system in the organization:

**TP Orthodontics, Inc.**

**100 Center Plaza**

**La Porte, Indiana 46350-9672 UNITED STATES**

for manufacture and final inspection of medical devices, class IIa

**Non-sterile orthodontic brackets, wires, their respective  
auxiliaries, adhesives, lingual devices, bands, elastics, elastomers  
and fixed functional appliances**

*The list of medical devices covered by this certificate is provided in the annex 1, 2, 3*

complies with requirements  
of Annex V to Directive 93/42/EEC (as amended) implemented into Polish law,  
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: **from 21.05.2021 to 26.05.2024**

The date of issue of the Certificate: **21.05.2021**

The date of the first issue of the Certificate: **06.04.2021**



Issued under the Contract No. MD-45/2021  
Application No: 532/2021  
Certificate bears the qualified signature.  
Warsaw, 21/05/2021  
Module **D1/2/3/4**  
FBM-27-E\_9

**Vice-President**



## ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-MDD-385/2021**

*List of medical devices covered by the certificate:*

Product Family	Product Sub-Group	Model/Type
Adhesives	Adhesives	eXact Clear Light Cure Adhesive
		Enamel Conditioner
	Ceramic Brackets with Pre-Applied Adhesive	ClearVu
		InVu
		Tip-Edge PLUS
	Metal Brackets with with Pre-applied Adhesive	Nu-Edge NX
		Tip-Edge PLUS NX
Auxillaries	Crimpable Hooks and Stops	Coated Crimpable Hooks
		Ribbed Crimpable Hooks
		Crimpable Stop
		Solderable Stops
	Springs	Rotating Springs
		Uprighting Springs
		Self-Locking Springs
	Traction Hooks	Round Traction Hook
		Square Traction Hook
		Traction Hook With Chain
		Rumely Traction Hook with Chain
Ceramic Brackets	Ceramic Brackets	ClearVu Mini Ceramic
		InVu Mini Ceramic
		InVu Ceramic
		Tip-Edge PLUS Ceramic
Elastics and Elastomers	Chain elastics	E-Links Modules
		E-Chain
		Elast-O Chain



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Warsaw, 21/05/2021

Vice-President



## ANNEX 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-MDD-385/2021**

*List of medical devices covered by the certificate:*

Product Family	Product Sub-Group	Model/Type
Elastics and Elastomers	Chain elastics	Super Slick Chain
	Elastics and elastomeric thread	Tru-Force Latex Elastics
		Slip Free Zing String
		Elastomeric Thread
		Elastic Thread
	Elastomeric ligatures	Slip Free Zing-O String
		Lig-A-Ties Elastomeric Ligatures
		Mini Stix Ligature Ties
	Orthodontic Separator	Carousel Ligature Ties
		Sep-A-Rings Separators
Fixed Functional Appliances	Fixed Functional Appliances	Super Slick Stick Separators
		Tubing
		Bump-R-Sleeve Tubing
Lingual Devices and Bands	Bands	Flip-Lock Herbst
		VektorPRO
	Lingual Buttons, Hooks, and Cleats	GripTite Bands
		Pre-Fit Bands
		Lingual Buttons
		Lingual Hooks
	Lingual Molar Sheaths	Lingual Cleats
		Lingual Molar Sheaths
	Lingual Retainers and Splints	Lingual Sheath
		Lingual Retainers
Metal Brackets and Tubes	Metal Brackets	Splints
		Nu-Edge
		Tip-Edge



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 Warsaw, 21/05/2021

**Vice-President**



## ANNEX 3 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No **1434-MDD-385/2021**

*List of medical devices covered by the certificate:*

Product Family	Product Sub-Group	Model/Type
Metal Brackets and Tubes	Metal Brackets	Nu-Edge Self-Ligating
		Straight-Edge II
		Advant-Edge
		Nu-Edge Mini
		Tip-Edge PLUS
		Tip-Edge Rx-1
	Tubes	Ultra Low Profile Molar Tubes
		First Molar Tubes for Tip-Edge Brackets
		Single Molar Tubes
Wires	Nickel Titanium Wires	Nickel Titanium Wires
	Stainless Steel Wires	Stainless Steel Wires
		Stainless Steel Wires



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**Vice-President**