EU Quality Management Certificate

This is to certify that the company

TP Orthodontics, Inc.

100 Center Plaza
La Porte, IN 46350
United States of America

SRN: US-MF-000020559

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	31620827 MDR2017Q
Certificate ID	1000206350
Effective date	2026-04-01
Expiry date	2031-02-25
Frankfurt am Main,	2026-04-01

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Annex to EU Quality Management Certificate
SRN of Manufacturer: US-MF-000020559
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Authorised Representative of the company:

Advena

Tower Business Centre, 2nd Flr.
Tower Street, Swatar BKR 4013
MALTA

SRN: MT-AR-000000234

Device categories and variants covered by this certificate according to Article 52:

Device category:	**MDN 1209 - Non-active non-implantable dental materials**
Product name:	VektorPRO, 610-5xx, 610-5XX PX Flip-Lock Herbst, 610-4XX
Risk classification:	IIa
Basic-UDI-DI:	0192029FixFunctionalUCKU 0192029FixFunctionalUBKS
Intended purpose:	Intended for orthodontic treatment of class II malocclusions.

Device category:	**MDN 1209 - Non-active non-implantable dental materials**
Product name:	Nu-Edge, Mini, 293-XXX, 293-XXXX Nu-Edge, Standard, 293-XXX, 293-XXXX Tip-Edge, 296-XXX PLUS SL 296-XXXSX Nu-Edge Self-Ligating, 293-XXX SL Straight-Edge, 290-XXX to 292-XXX Advant-Edge, 294-XXX to 295-XXX Molar Tubes, 391-XXX, 210-XXX First Molar Tubes for Tip-Edge, 391-XXX Ultra Low Profile Tubes, 391-XXX
Risk classification:	IIa
Basic-UDI-DI:	0192029MetalBracketsQW 0192029MetalTubes86
Intended purpose:	Component of the fixed orthodontic appliance that serve as a point for attachment for the orthodontic arch wire, lock pins, or any necessary auxiliaries onto the tooth.

Annex to EU Quality Management Certificate
SRN of Manufacturer: US-MF-000020559
Certificate ID: 1000206350

Device category:	**MDN 1209 - Non-active non-implantable dental materials**
Product name:	ClearVu, 297-XXX CV InVu, 297-XXX InVu Mini, 297-XXX Tip-Edge PLUS Ceramic, 297-XXX
Risk classification:	IIa
Basic-UDI-DI:	0192029CeramicBracketsN9
Intended purpose:	Component of the fixed orthodontic appliance that functions as a point for attachment for the orthodontic arch wire, lock pins, or any necessary auxiliaries onto the tooth. The bracket is bonded to the tooth and they serve primarily as a mean of transferring applied stresses to achieve a clinically desired movement of the teeth.

Device category:	**MDN 1209 - Non-active non-implantable dental materials**
Product name:	Traction Hooks, 224-XXX Crimpable Hook, 226-XXX, 226-XXX W Crimpable Stop, 226-XXX, 226-XXX W Springs, 240-XXX, 214-XXX, 351-XXX to 354-XXX
Risk classification:	IIa
Basic-UDI-DI:	0192029Auxiliaries3F
Intended purpose:	The auxiliaries are used to assist with the orthodontic mechanics in patients undergoing orthodontic treatment to correct malocclusion.

Device category:	**MDN 1209 - Non-active non-implantable dental materials**
Product name:	Reflex Nickel-Titanium Wire, 381-XXX to 387-XXX, 381-XXX W Reflex Heat-Activated Nickel Titanium Wire, 381-XXX to 387-XXX Braided 8-Strand Reflex Nickel-Titanium Wire, 381-XXX-, 381-XXX-W Bow-Flex Wire, 230-XXX, 335-XXX, 336-XXX, 338-XXX, 358-XXX TP Original Wire, 229-XXX to 238-XXX, 336-XXX, 338-XXX Shiny Bright Wire, 380-XXX to 387-XXX, 381-XXX W Rounded Rectangular Wire, 380-XXX Twisted 3-Strand Wire, 381-XXX Co-Ax Wire, 231-XXX, 281-XXX, 381-XXX Woven 8-Strand Wire 381-XXX Tip-Edge Wires, 336-XXX to 339-XXX Pretorqued Archwires, 381-XXX Ligature Wire, 281-XXX, 382-XXX TP Original Lab Wire, 706-XXX
Risk classification:	IIa
Basic-UDI-DI:	0192029WiresBJ
Intended purpose:	Wires are intended to be used along with the fixed orthodontic appliance to treat malocclusions.

Annex to EU Quality Management Certificate
SRN of Manufacturer: US-MF-000020559
Certificate ID: 1000206350

Device category:	**MDN 1209 - Non-active non-implantable dental materials**
Product name:	exact® Clear Light Cure Adhesive, 151-XXX
Risk classification:	IIa
Basic-UDI-DI:	0192029AdhesivesWP
Intended purpose:	Indicated for use as an orthodontic bonding agent for metal brackets, ceramic brackets, and buccal tubes to the tooth's surface.

Device category:	**MDN 1209 - Non-active non-implantable dental materials**
Product name:	Enamel Conditioner, 150-XXX
Risk classification:	IIa
Basic-UDI-DI:	0192029AdhesivesWP
Intended purpose:	Indicated for etching enamel and dentin to promote adhesion of primer/ bonding agent adhesives to tooth structure and restorative materials.

Device category:	**MDN 1209 - Non-active non-implantable dental materials**
Product name:	ClearVu® Ceramic Brackets with Pre-Applied Adhesive, 297-XXX CVX InVu® Ceramic Brackets with Pre-Applied Adhesive, 297-XXX RBX or 297-XXX MRX Tip-Edge® PLUS Ceramic Brackets with Pre-Applied Adhesive, RB 297-XXX Nu-Edge NX, 293-XXX NX Tip-Edge PLUS NX Brackets, 296-XXX NX
Risk classification:	IIa
Basic-UDI-DI:	0192029AdhesivesWP
Intended purpose:	Intended for orthodontic appliance application and bonding for orthodontic treatment.

Device category:	**MDN 1209 - Non-active non-implantable dental materials**
Product name:	Tru-Force® Latex Elastics, 360-XXX to 362-XXX, 370-XXX to 372-XXX Lig-A-Ties Elastomeric Ligatures, 281-XXX Elastomeric Ligature Ties, 361-XXX, 382-XXX, 383-XXX E-Links® Modules, 384-XXX, 389-XXX E-Chain, 383-XXX to 390-XXX Elast-O chain, 386-050 Super Slick® Chain, 388-XXX to 390-XXX Slip Free Zing String® Elastomeric Thread, 100-XXX Elastic Thread, 100-XXX Slip Free Zing-O® String, 100-XXX Bump-R-Sleeve® Tubing, 100-XXX Separators, 352-XXX, 353-XXX
Risk classification:	IIa
Basic-UDI-DI:	0192029ElasticsC3
Intended purpose:	Assist with the orthodontic mechanics in patients undergoing orthodontic treatment to correct malocclusion.

Annex to EU Quality Management Certificate
SRN of Manufacturer: US-MF-000020559
Certificate ID: 1000206350

Device category:	**MDN 1209 - Non-active non-implantable dental materials**
Product name:	Lingual Buttons, 224-XXX Lingual Hooks, 224-XXX to 226-XXX Lingual Cleats, 224-XXX Lingual Sheath, 328-XXX Lingual Retainers, 224-XXX Splints, 224-XXX Grip-Tite Bands, 964-XXX to 967-XXX Pre-Fit Bands, 940-XXX to 947-XXX
Risk classification:	IIa
Basic-UDI-DI:	0192029LingualDevicesAC 0192029LingualBands7B
Intended purpose:	Assist with the orthodontic mechanics in patients undergoing orthodontic treatment to correct malocclusion.

Examinations and tests performed:
31620827_A216163MED_01 dated 2025-08-19
31620827_A215608MED_TF Fixed Functional Appliances dated 2025-06-24

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Version	Date of Issue	Certificate-ID	Description of change
01	n/a	n/a	Initial