



CERTIFICATE

EC No 1434-MDD-459/2019
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:

American Orthodontics Corp
3524 Washington Avenue
Sheboygan, Wisconsin 53081 UNITED STATES

for manufacture and final inspection of medical devices, class: IIa

**Non-sterile Orthodontic, Burs, Wires, Wire Locks,
Springs, and Dental and Palatal Correctors**

Products list in attachments: 1, 2

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 29.08.2019 to 04.03.2024

The date of issue of the Certificate: 29.08.2019



Application No: 529/2019
Module D1/2/3/4

Michał Pachowski, Ph.D.
President



Certificate No. **1434-MDD-459/2019**
Issued under the Contract No. **MD-81/2019**
Bears the PCBC hologram
Warsaw, 29/08/2019



ANNEX 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No **1434-MDD-459/2019**

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type
Fixed, Functional & Extra Oral Devices	Dental and Palatal Correctors	Quad Helix
		Alexander Lip Bumper
		Palatal Arches
Orthodontic Bonding Agents	Sealants / Coatings	Bracepaste MTP Primer™
Orthodontic Supplies	Orthodontic Burs	Debonding Bur - carbide
		Debonding Burs - Diamond
Orthodontic Wire, Springs and Attachments	Orthodontic Wire	Superelastic Titanium Memory
		Multiphase Blue Chromium Cobalt Wire
		Power Pin
		Gold Coated
		Beta Titanium Wire
		Stainless Steel Wire
		Force Two NiTi Wire
		Gold Tone
		Stainless Steel Multi-Strand
		Stainless Steel Springs
		Uprighting Spring
		Rotation Spring
		Compliance Spring
		Kilroy Spring
		Auxiliary Light Torquing Arch
		Ulysses/Extrusion Spring
		Nickel Titanium Memory Springs
NiTi Springs		
Kobayashi Hooks		



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Annex 1 to certificate No. **1434-MDD-459/2019**
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ANNEX 2 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No 1434-MDD-459/2019

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type
Orthodontic Wire, Springs and Attachments	Orthodontic Wire	Orientation Pin
		Therma-Ti®
		Tritanium™
	Orthodontic Wire Attachment - Locks	Monkey Hook




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Annex 2 to certificate No. **1434-MDD-459/2019**
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