



# CERTIFICATE

**EC Certificate No. 1434-MDD-401/2021**

**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:

**American Orthodontics Corp**

**3524 Washington Avenue**

**Sheboygan, Wisconsin 53081 UNITED STATES**

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

**Non-sterile Orthodontic, Burs, Wires, Wire Locks,  
Springs, Elastomers, Adhesives, Sealants /  
Coatings, and Dental and Palatal Correctors**

*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 25.05.2021 to 04.03.2024

The date of issue of the Certificate: 25.05.2021

The date of the first issue of the Certificate: 29.08.2019



Issued under the Contract No. MD-143/2020  
Application No: 589/2020  
Certificate bears the qualified signature.  
Warsaw, 25/05/2021  
Module D1/2/3/4  
FBM-27-E\_9

Anna  
Małgorzata  
Wyroba  
Vice-President  
Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.05.25  
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# ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-MDD-401/2021**

*List of medical devices covered by the certificate:*

Product Family	Product Sub-Group	Model/Type
Elastomerics	Elastomerics	Arch Wire Sleeve
		Plastic Tie
		E-Z Tie Tubing
Fixed, Functional & Extra Oral Devices	Dental and Palatal Correctors	Quad Helix
		Alexander Lip Bumper
		Palatal Arches
		Expansion Screw
Orthodontic Bonding Agents	Adhesives	BracePaste
		Acid Etchant
Orthodontic Brackets & Bondable Devices	Sealants / Coatings	Bracepaste
	Bondable, Ceramic	Ceramic Button
	Bondable, Metal	Eruption Appliance
Orthodontic Supplies	Orthodontic Burs	Orthodontic Brackets, Ceramic
		20/40 Ceramic Brackets
Orthodontic Wire, Springs and Attachments	Orthodontic Archwire	Debonding Bur - carbide
		Debonding Burs - Diamond
		Superelastic Titanium Memory
		Multiphase Blue Chromium Cobalt Wire



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 Warsaw, 25/05/2021

Anna  
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 Wyroba  
 Vice-President

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## ANNEX 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-MDD-401/2021**

*List of medical devices covered by the certificate:*

Product Family	Product Sub-Group	Model/Type
Orthodontic Wire, Springs and Attachments	Orthodontic Archwire	Gold Coated
		Beta Titanium Wire
		Stainless Steel Wire
		Force Two NiTi Wire
		Gold Tone
		Stainless Steel Multi-Strand
		Therma-Ti®
		Tritanium™
Orthodontic Wire, Springs and Attachments	Orthodontic Springs	Warren Spring
	Orthodontic Wire	Stainless Steel Springs
		Uprighting Spring
		Rotation Spring
		Compliance Spring
		Kilroy Spring
		Auxiliary Light Torquing Arch
		Ulysses/Extrusion Spring
		Nickel Titanium Memory Springs
		NiTi Springs

**CE 1434**

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## ANNEX 3 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-MDD-401/2021**

*List of medical devices covered by the certificate:*

Product Family	Product Sub-Group	Model/Type
Orthodontic Wire, Springs and Attachments	Orthodontic Wire	Kobayashi Hooks
		Orientation Pin
	Orthodontic Locks - Stops and Hooks	Monkey Hook
		Power Pin



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Warsaw, 25/05/2021

Anna  
Małgorzata  
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**Vice-President**