



CERTIFICATE

EC Certificate No. 1434-MDD-400/2021

**Full Quality Assurance System
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 the design, manufacture and final inspection of medical devices, class: Class IIa

**non-sterile Orthodontic Bands, Brackets, Bondable
Attachments, Buccal Tubes, Elastomers, Wires, Springs,
Malocclusion Correctors and Dental & Palatal
Correctors**

The list of medical devices covered by this certificate is provided in the Annex 1, 2, 3, 4, 5

**complies with requirements of Annex II (excluding Section 4) 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 20.11.2022

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: 588/2020
Certificate bears the qualified signature.
Warsaw, 25/05/2021
Module H2/3/4/5
FBM-26-E_9

Anna
Małgorzata
Wyroba

Elektronicznie
podpisany przez Anna
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Data: 2021.05.25
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Vice-President



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-400/2021

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type	
Fixed and Functional and extra Oral Devices	Dental & Palatal Correctors	Spring Jet	
		Mesial Jet	
		Uprighter Jet	
		Rapid Molar Intruder	
		M.A.P. Mini Activator Posturer	
	Malocclusion Correctors	Distal Jet	
		Jumpers	
		Jones Jig™	
		Quick Fix	
		Lip Bumper	
		Hanks Telescoping Herbst®	
		Miniscope™ Telescoping Herbst®	
		Herbst™ Appliance	
		Powerscope™ 2	
	Orthodontic Bands & Attachments	Orthodontic Band Attachments	Lingual Sheaths
			Cleats
			Elastic Lugs
		Orthodontic Bands	Contoured
Anteriors			



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ANNEX 2 TO THE CERTIFICATE
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No 1434-MDD-400/2021

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Orthodontic Bands & Attachments	Orthodontic Bands	MRX Bands
		MR
		MR1
		MR2
		Rollo Bands
		Mini Skirt™ Crowns
Orthodontic Brackets & Bondable Devices	Bondable, Ceramic	Ceramic Button
	Bondable, Metal	Buttons
		Ball Hooks
		Eyelets
		Coil Eyelet
		Space Maintainer
		Bondable Retainer
		Bite Blocks
		Tongue Director
		SL Bracket
	Orthodontic Bracket - Metal	Empower® 2
		Mini Master Series™
		LP® Low Profile



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ANNEX 3 TO THE CERTIFICATE

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List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Orthodontic Brackets & Bondable Devices	Orthodontic Bracket - Metal	Iconix™
		Master Series™
		Mini Standard Edgewise
		Mini Tweed
		Forever Gold™ 24K
		Custom Rx
	Orthodontic Bracket, Ceramic	Empower Clear™
		Radiance Plus™
	Orthodontic Bracket, Plastic	Silkon Plus
	Orthodontic Power Arm	UT Hooks
Orthodontic Buccal Tubes	Buccal Tubes	Piggyback Tubes
		Dr. Korn Tube
		Inconel
		Funneled Entrance
		Non Convertible
		Non Convertible Double
		Non Convertible Triple
		Non Convertible Lip Bumper



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ANNEX 4 TO THE CERTIFICATE
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List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Orthodontic Buccal Tubes	Buccal Tubes	Non Convertible WRAPAROUND
		Convertible Single
		Convertible Double
		Convertible Triple
		Nola Buccal Tube
		DB Tube Gold
		Master Series™
		iFit®
		Slim Tube™
		LP® Low Profile
		Empower® 2
Mini Master Series™		
Orthodontic Elastomerics	Latex Elastomerics	The Wildlife Series™ Elastics
	Non-Latex Elastomerics	Sea Life Elastics
		Colored Chain
		Memory Chain
	Ligatures	
Orthodontic Separator	Separators	



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ANNEX 5 TO THE CERTIFICATE
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List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Orthodontic Wires, Springs & Attachments	Orthodontic Archwire	Tanzo™
		NT3™
		Iconix Wire
	Orthodontic Springs	Separating Spring
		ART Auxiliary Springs
	Orthodontic Wire	Wrap Around Hawley Retainer
		Ball Retainer Clasps
		Ligature Wire
		Stainless Steel Wire
	Orthodontic Wire Attachments - Locks	Weldable Stop
		Surgical Hook
		Arch Hook
		Arch Lock
		Diastema
		Power Hook
		Crimpable Stop



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