



CERTIFICATE

EC Certificate No. 1434-MDD-259/2020
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,
and Dental and Palatal Correctors**

The list of medical devices covered by this certificate is provided in the Annex 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 23.06.2020 to 04.03.2024

The date of issue of the Certificate: 23.06.2020

The date of the first issue of the Certificate: 29.08.2019



Issued under the Contract No. MD-40/2020
Application No: 508/2020
Certificate bears the qualified signature.
Warsaw, 23/06/2020
Module D1/2/3/4
FBM-27_E_8

Anna
Małgorzata
Wyroba

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2020.06.23
16:00:31 +02'00'

Mgr Anna Wyroba
Vice-President



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-259/2020

List of medical devices covered by the 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™
	Adhesives	BracePaste™
		Acid Etchant (Gel, Liquid)
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		



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 Warsaw, 23/06/2020

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 Małgorzata Wyroba
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Mgr Anna Wyroba
 Vice-President



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-259/2020

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
		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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