



EC CERTIFICATE

American Orthodontics Corp

3524 Washington Avenue
Sheboygan, WI 53081 UNITED STATES

Full Quality Assurance System Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Design and Manufacture of Stainless Steel Brackets, Orthodontic Buccal Tubes, Orthodontic Bands, Fixed & Functional Products, Stops & Hooks, Composite (Plastic) Brackets, Ceramic Brackets, Elastomeric Products, Orthodontic Wire Products, Lingual Attachments, and Orthodontic Wire – Springs.

Device Classifications:

Class IIa

Device Descriptions and Model Type:

Please refer to Attachments: 1, 2, 3, 4, 5

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 5 attachments listing product references covered by this certificate.

File Number A4041
Certificate Number 840.180522
Initial Issue Date February 1, 2017

Cycle Start Date November 21, 2017
Effective Date May 22, 2018
Expiry Date November 20, 2022

Authorised by

Paul Daysh

Medical Notified Body Operations Manager
For and on Behalf of UL International (UK) Ltd



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Attachment 1 of 5

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

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Lingual Attachments	Orthodontic Clamp, Wire	Buttons	Class IIa	38741
		Ball Hooks	Class IIa	38741
		Lingual Sheaths	Class IIa	38741
		Eyelets	Class IIa	38741
		Coil Eyelet	Class IIa	38741
		Low Profile Cleats	Class IIa	38741
		Gull Wing Cleats	Class IIa	38741
		Elastic Lugs	Class IIa	38741
		Seating Lugs	Class IIa	38741
Bands	Orthodontic Band, Material	Band Material	Class IIa	46338
Ceramic Brackets	Self-Ligating Orthodontic Bracket Orthodontic Bracket, Ceramic	Empower Clear™	Class IIa	58818
		Radiance Plus™	Class IIa	58937
Composite Brackets	Orthodontic Bracket, Plastic, Single-Use	Silkon Plus	Class IIa	46582
Elastomers	Orthodontic Band, Elastic	The Wildlife Series™	Class IIa	38733
		Sea Life Elastics	Class IIa	38733
		Colored Chain	Class IIa	38733
		Memory Chain	Class IIa	38733
		Orthodontic Archwire/Bracket Ligature	Class IIa	47827
Stops and Hooks	Orthodontic Clamps/Locks/Hooks	Weldable Stop	Class IIa	38741
		Surgical Hook	Class IIa	38741

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Attachment 2 of 5

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

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Stops and Hooks	Orthodontic Clamps/Locks/Hooks	Arch Hook	Class IIa	38741
		Arch Lock	Class IIa	38741
		Monkey Hook	Class IIa	38741
Buccal Tubes	Orthodontic Tubes	Empower®	Class IIa	31759
		Empower® 2	Class IIa	31759
		Mini Master Series™	Class IIa	31759
		Master Series™	Class IIa	31759
		iFit®	Class IIa	31759
		LP® Low Profile	Class IIa	31759
		Slim Tube™	Class IIa	31759
		Cross Tubes	Class IIa	31759
		Piggyback Tubes	Class IIa	31759
		Dr. Korn Tube	Class IIa	31759
		Inconel	Class IIa	31759
		Funneled Entrance	Class IIa	31759
		Non Convertible	Class IIa	31759
		Non Convertible Double	Class IIa	31759
		Non Convertible Triple	Class IIa	31759
Non Convertible Lip Bumper	Class IIa	31759		
Non Convertible	Class IIa	31759		
		WRAPAROUND		

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Attachment 3 of 5

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

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Buccal Tubes	Orthodontic Tubes	Convertible Single	Class IIa	31759
		Convertible Double	Class IIa	31759
		Convertible Triple	Class IIa	31759
		Nola Buccal Tube	Class IIa	31759
		DB Tube Gold	Class IIa	31759
Fixed & Functional	Orthodontic Appliance System, Adjustable	Distal Jet	Class IIa	41678
		Spring Jet	Class IIa	41678
		Mesial Jet	Class IIa	41678
		Uprighter Jet	Class IIa	41678
		Jasper Jumper	Class IIa	41678
		Gentle Jumper	Class IIa	41678
		Jones Jig™	Class IIa	41678
		Rapid Molar Intruder	Class IIa	41678
		M.A.P. Mini Activator	Class IIa	41678
		Posturer		
		Mandibular Advancer	Class IIa	41678
		Quick Fix	Class IIa	41678
		Lip Bumper	Class IIa	41678
		Cantilever Bar Offset	Class IIa	41678
		Hanks Telescoping Herbst®	Class IIa	41678
Miniscope™ Telescoping Herbst®	Class IIa	41678		

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Attachment 4 of 5

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

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code	
Fixed & Functional	Orthodontic Appliance System, Adjustable	Herbst™ Appliance	Class IIa	41678	
		Powerscope™ 2	Class IIa	41678	
		Alexander Lip Bumper	Class IIa	41678	
	Orthodontic Space Maintainer	Bondable Space Maintainer	Class IIa	31754	
		Bondable Retainer (Alexander Flat Bow Retainer 855-155, 156, 157)	Class IIa	35310	
		Bondable Retainer	Class IIa	35310	
	Orthodontic Retainer		Bite Blocks	Class IIa	35310
			Tongue Director	Class IIa	35310
			Diastema	Class IIa	35310
				Class IIa	35310
Orthodontic Wire	Orthodontic Wire	Tanzo™	Class IIa	16204	
		NT3™	Class IIa	16204	
		Superelastic Titanium Memory	Class IIa	16204	
		Everwhite™ Wire	Class IIa	16204	
		Wrap Around Hawley Retainer	Class IIa	16204	
		Multiphase Blue Chromium	Class IIa	16204	
		Cobalt Wire	Class IIa	16204	
	Orthodontic Archwire/Bracket Ligature		Ball Retainer Clasps	Class IIa	41677
			Ligature Wire	Class IIa	41677
				Class IIa	41677
Stainless Steel Brackets	Orthodontic Bracket, Metal	LP® Low Profile	Class IIa	46581	
		Empower® 2	Class IIa	46581	
		Mini Master Series™	Class IIa	46581	

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Stainless Steel Brackets	Orthodontic Bracket, Metal	Master Series™	Class IIa	46581
		T3™	Class IIa	46581
		Mini Standard Edgewise	Class IIa	46581
		Mini Tweed	Class IIa	46581
		Iconix™	Class IIa	46581
		Forever Gold™ 24K	Class IIa	46581
		Metal Custom Rx	Class IIa	46581
		Stealth™ Lingual	Class IIa	46581
Bands	Orthodontic Band, Preformed	MRX Bands	Class IIa	38734
		MR	Class IIa	38734
		MR1	Class IIa	38734
		MR2	Class IIa	38734
		MR3	Class IIa	38734
		Contoured	Class IIa	38734
		Rollo Bands	Class IIa	38734
		Anteriors	Class IIa	38734
		Mini Skirt™ Crowns	Class IIa	38734
Stops and Hooks	Orthodontic Clamps/Locks/Hooks	Power Hook	Class IIa	38741
		Crimpable Stop	Class IIa	38741

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