



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 Classification:
Ila

G/UMDN Code:
See Attachments

Device Descriptions:
See Attachments

Model Type:
See Attachments

We hereby declare that an examination of the full quality assurance system has been carried out per report SR4071886, 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 4 attachments listing model numbers covered by this certificate.

File Number A4041
Certificate No. 840.170512

Cycle Start Date 01 February 2017
Effective Date 12 May 2017
Expiry Date 22 November 2017

Authorised by

Deborah Stubbs
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843



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Attachment 1 of 4

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

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Bands	Orthodontic Band, Preformed	MRX Bands MR MR1 MR2 MR3 Contoured Rollo Bands Anteriors Mini Skirt™ Crowns	Ila	38734
Bands	Orthodontic Band, Material	Band Material	Ila	46338
Ceramic Brackets	Orthodontic Bracket, Ceramic	Radiance Plus™	Ila	58937
Ceramic Brackets	Self-Ligating Orthodontic Bracket	Empower Clear™	Ila	58818
Composite Brackets	Orthodontic Bracket, Plastic, Single-Use	Silkon Plus	Ila	46582
Elastomerics	Orthodontic Band, Elastic	The Wildlife Series™ Sea Life Elastics Colored Chain Memory Chain	Ila	38733
Elastomerics	Orthodontic Archwire/Bracket Fixation	Ligatures	Ila	47828
Stops and Hooks	Orthodontic Clamps/Locks/Hooks	Power Hook Crimpable Stop Weldable Stop Surgical Hook Arch Hook Arch Lock Monkey Hook	Ila	38741

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Attachment 2 of 4

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 Tube	Empower® Empower® 2 Mini Master Series™ Master Series™ iFit® LP® Low Profile Slim Tube™ Cross Tubes Piggyback Tubes Dr. Korn Tube Inconel Funneled Entrance Non Convertible Non Convertible Double Non Convertible Triple Non Convertible Lip Bumper Non Convertible WRAPAROUND Convertible Single Convertible Double Convertible Triple Nola Buccal Tube DB Tube Gold	Ila	31759

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Attachment 3 of 4

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Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Fixed & Functional	Orthodontic Appliance System, Adjustable	Distal Jet	IIa	41678
		Spring Jet		
		Mesial Jet		
		Uprighter Jet		
		Jasper Jumper		
		Gentle Jumper		
		Jones Jig™		
		Rapid Molar Intruder		
		M.A.P. Mini Activator		
		Posturer		
		Mandibular Advancer		
		Quick Fix		
		Lip Bumper		
		Cantilever Bar Offset		
		Hanks Telescoping		
		Herbst®		
		Miniscope™		
Telescoping Herbst®				
Herbst™ Appliance				
Powerscope™ 2				
Fixed & Functional	Orthodontic Space Maintainer	Bondable Space Maintainer	IIa	31754
Fixed & Functional	Orthodontic Retainer	Bondable Retainer	IIa	35310
		Bite Blocks		
		Tongue Director		
		Diastema		

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Attachment 4 of 4

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	Lingual Sheaths Eyelets Coil Eyelet Low Profile Cleats Gull Wing Cleats Elastic Lugs Seating Lugs Buttons Ball Hooks	Ila	46581
Orthodontic Wire	Orthodontic Wire	Tanzo™ NT3™ Superelastic Titanium Memory Everwhite™ Wire Wrap Around Hawley Retainer	Ila	16204
Stainless Steel Brackets	Orthodontic Bracket, Metal	LP® Low Profile Empower® 2 Mini Master Series™ Master Series™ T3™ Mini Standard Edgewise Mini Tweed Forever Gold™ Forever Gold™ 24K Metal Custom Rx Stealth™ Lingual	Ila	46581

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