



EC CERTIFICATE

American Orthodontics Corp

3524 Washington Avenue
Sheboygan, WI 53081 United States

Full Quality Assurance System Approval Certificate

Annex II (excluding section 4.0) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Design and manufacture of dental adhesives and sealants.

Device Classification:
Ila

G/UMDN Code:
See Attachment

Device Descriptions:
See Attachment

Model Type:
See Attachment

We hereby declare that an examination of the full quality assurance system has been carried out per report SR3710636, 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 1 attachments listing model numbers covered by this certificate.

File Number A4041
Certificate No. 856.170201

Cycle Start Date 01 February 2017
Effective Date 01 February 2017
Expiry Date 01 June 2018

Authorised by

Deborah Stubbs
Certification Manager

For and on Behalf of UL International (UK) Ltd

Notified Body
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Attachment 1 of 1

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

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code	
Adhesives	Glass Ionomer Dental Cement	Bandtite™ Band Cement	Ila	16704	
		Orthodontic Bracket Adhesive	Ila	31750	
	Dental Etching Composite	Dental Etching Composite	No Mix: 30™	Ila	31750
			Eagle FluorSure™	Ila	31750
			Acid Etching (Gel, Semi-Gel, Liquid)	Ila	36153
		Dental Conditioner	Porcelain Conditioner	Ila	34771
		Orthodontic Bracket Adhesive	Eagle Spectrum™	Ila	31750
	Eagle No Drift™		Ila	31750	
	Eagle MTP™		Ila	31750	
	Dental Sealant	Eagle Sealant	Ila	34771	
		Sealant	Ila	34771	

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