



EC CERTIFICATE

American Orthodontics Corp

3524 Washington Avenue
Sheboygan, WI 53081 United States

Production Quality Assurance System Approval Certificate

Annex V, section 3 of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Manufacture of orthodontic brackets and wire clamps.

Device Classification:
Ila

G/UMDN Code:
See Attachments

Device Descriptions:
See Attachments

Model Type:
See Attachments

We hereby declare that an examination of the production 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 V of Council Directive 93/42/EEC on Medical Devices. We certify that the production 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 V, Section 4. For Class IIb & III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex III is required. This certificate is issued with 1 attachments listing model numbers covered by this certificate.

File Number A4041
Certificate No. 860.170201

Cycle Start Date 01 February 2017
Effective Date 01 February 2017
Expiry Date 20 April 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
Ceramic Brackets	Orthodontic Bracket, Ceramic	20/40 Ceramic	Ila	58937
Lingual Attachments	Orthodontic Clamp, Wire	Ceramic Button	Ila	46581

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