



# 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 bands and wires.**

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. 861.170201

Cycle Start Date 01 February 2017  
Effective Date 01 February 2017  
Expiry Date 15 December 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 1

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

| Product Family      | Product Sub-Group               | Model/Type         | Classification | G/UMDN Code |
|---------------------|---------------------------------|--------------------|----------------|-------------|
| Elastomerics        | Orthodontic Space<br>Maintainer | Separators         | Ila            | 31754       |
| Lingual Attachments | Orthodontic Clamp,<br>Wire      | Eruption Appliance | Ila            | 46581       |

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