

# Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

**Company Information:**

American Orthodontics  
3524 Washington Avenue  
Sheboygan, WI 53081

**Certificate Number:** 201805 -10

**Medical Device Detail:**

**Product/Family Category:** Bonding Agents

**Classification:** Class IIa *per Rule # 5, 3rd indent*  
*Classification is according Directive 93/42/EEC; Annex IX*

**Product(s) Tradename(s):**

See Attachment A

**GMDN Code:**

See Attachment A

**CE Authorized Representative:**

MT Promedt Consulting GmbH  
Altenhofstrasse 80  
66386 St. Ingbert  
Germany

**Assessment Details:**

**Notified Body:** UL International (UK) Ltd.  
**CE Certificate #:** 840.180522  
**Notified Body #:** 0843  
**Issue Date:** 05/22/18  
**Route of Directive:** Annex II  
*of the Directive 93/42/EEC on Medical Devices.*

**Standards Applied:**

**Harmonized Standards:** EN ISO 13485, IEC 62336, EN ISO 14971, EN 1041, EN ISO 10993-1, 10993-3, 10993-5, 10993-11

**Other Standards:** ISO 10993-10, ISO 15223-1, ISO 15223-2

**Declaration statement:**

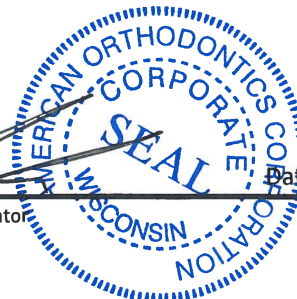
*Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the safety and performance principles and the classifications rules before being shipped. The above products are in compliance with Annex I Essential Requirements under Directive 93/42/EEC on Medical Devices. All supporting documentation is retained under the premises of the manufacturer.*

**Signed for and on behalf of:**

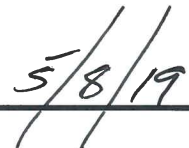
American Orthodontics  
Sheboygan, WI

**Company Representative:**

  
Andre Leak / Regulatory Affairs Coordinator



Date:



**ATTACHMENT A**

**Product/Family Category:** Bonding Agents

**Classification:** Class IIa *per Rule # 5, 3rd indent*

*Classification is according Directive 93/42/EEC; Annex IX*

**Product(s) Tradename(s):**

**GMDN Code:**

BracePaste™ Adhesive	31750
No Mix:30™ Adhesive	31750
Eagle Spectrum™ Adhesive	31750
Eagle No Drift™ Adhesive	31750
Bandtite™ Band Cement	31750
MR Lock LC™ Cement	31750
Porcelain Conditioner	34771
Eagle Spectrum™ Sealant	34771
Eagle FluorSure™ Sealant	34771
Eagle No Drift™ Sealant	34771
BracePaste™ MTP Primer	34771