

## Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

**Company Information:**

American Orthodontics  
3524 Washington Avenue  
Sheboygan, WI 53081

**Certificate Number:** 201603 -04a

**Certificate Issue Date:** 03/07/16

**Certificate Expiry Date:** 11/22/17

***This certificate is valid until Expiry Date listed above.***

**Medical Device Detail:**

**Product/Family Category:**

Buccal Tubes

**Classification:** *Classification is according to Directive 93/42/EEC, Annex IX*

*Class IIa per Rule 5, 3rd indent*

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

Slim Tube™  
iFit™ Tubes  
Nola Buccal Tube  
Inconel

**System(s)/Configuration(s) associated with Product(s) Tradename(s):**

Slim Tube™ (Direct Bond: Non Convertible: Mandibular 1st Molar, Mandibular 2nd Molar)  
Slim Tube™ (Direct Bond: Non Convertible: Maxillary 1st Molar)  
Slim Tube™ (Direct Bond: Convertible: Maxillary 2nd Molar)  
iFit™ Tubes (Direct Bond: Non Convertible: Maxillary 1st Molar, Maxillary 2nd Molar)  
iFit™ Tubes (Direct Bond: Non Convertible: Mandibular 1st Molar, Mandibular 2nd Molar)  
Inconel (Direct Bond: Non Convertible: Maxillary 2nd Molar, Mandibular 2nd Molar)

**CE Authorized Representative:**

Emergo Europe  
Molenstraat 15  
2513 BH The Hague, The Netherlands

**Assessment Details:**

**Notified Body:** TUV Austria

**CE Certificate #:** TUV-A-MT-1/13/QE011

**Issue Date:** 05/01/13

**Route of Directive:** Annex VI *of the Directive 93/42/EEC on Medical Devices.*

**Standards Applied:**

**Harmonized Standards:** IEC ISO 62336, EN ISO 14971, EN 1041, EN ISO 10993-1, 10993-3, 10993-5, 10993-10, 10993-11

**Other Standards:** ISO 10271, ISO 27020, ISO 7405, ISO 9333, ISO/TS 11405

**Declaration statement:**

*Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classifications rules before being shipped. The above products are in compliance with Annex I Essential Requirements of Directive 93/42/EEC. The product is CE marked.*

**Signed for and on behalf of:**

American Orthodontics  
Sheboygan, WI

**Company Representative:**



Trang Adams / Regulatory Affairs Specialist

