

## Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

**Company Information:**

American Orthodontics  
3524 Washington Avenue  
Sheboygan, WI 53081

**Certificate Number:** 201706 -05

**Certificate Issue Date:** 06/12/17

**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):**

Empower®  
Empower® 2  
Mini Master Series™  
Master Series™  
iFit®  
LP® Low Profile  
Slim Tube™  
Cross Tubes  
Piggyback Tubes  
Dr. Korn Tube  
Inconel

Funneled Entrance  
Non Convertible  
Non Convertible Double  
Non Convertible Triple  
Non Convertible Lip Bumper  
Non Convertible WRAPAROUND  
Convertible Single  
Convertible Double  
Convertible Triple  
Nola Buccal Tube  
DB Tube Gold

**CE Authorized Representative:**

Emergo Europe  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

**Assessment Details:**

**Notified Body:** UL International (UK) Ltd.

**CE Certificate #:** 840.170512

**Issue Date:** 05/12/17

**Route of Directive:** Annex II (excluding Sect. 4)

*of the Directive 93/42/EEC on Medical Devices.*

**Standards Applied:**

**Harmonized Standards:** EN ISO 13485, IEC 62336-1, EN ISO 14971, EN 1041, EN ISO 10993-1, 10993-3, 10993-5, 10993-11, EN 980

**Other Standards:** ISO 10993-10, ISO 7405, ISO 10271, ISO 27020, ISO 15223-1, ISO 15223-2, ISO 9333

**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

