

## Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

**Company Information:**

American Orthodontics  
3524 Washington Avenue  
Sheboygan, WI 53081

**Certificate Number:** 201805 -15a

**Certificate Issue Date:** 05/22/18

**Certificate Expiry Date:** 11/20/22

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

**Medical Device Detail:**

**Product/Family Category:** Orthodontic Instruments

**Classification:** Class I per Rule 5, 1st & 2nd indent  
*Classification is according to Directive 93/42/EEC, Annex IX*

**Intended Use:** American Orthodontics' products are used for the orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist.

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

Luno™  
MasterLine™  
Empower Instrument  
T3 Instruments  
Wire Bending Pliers  
Bracket & Band Placing Instrument (Direct Bond Bracket Holders, Positioner, Band Seater)  
Bracket & Band Placing Instrument (Band Pusher)  
Bracket & Band Placing Instrument (High Heat Bite Stick, Tweezers)  
Ligating Instruments (Ligature Director, Single End Explorer, Force Module Separator, Ligature Tying Pliers)  
Ligating Instruments (Mathieu Needle Holder, Smaha Forceps, Hemostat)  
PowerScope Magnetic Driver

**CE Authorized Representative:**

MT Promedt Consulting GmbH  
Altenhofstrasse 80  
66386 St. Ingbert  
Germany

**Assessment Details:**

**Route of Directive:** VII of the Directive 93/42/EEC on Medical Devices

**Standards Applied:**

**Harmonized Standards:** EN ISO 13485, IEC 62336, EN ISO 14971, EN 1041, EN 980

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

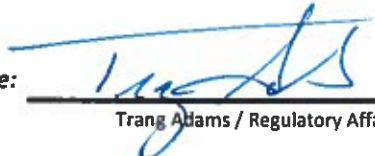
**Declaration statement:**

*This Declaration of Conformity is issued under the sole responsibility of American Orthodontics. 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 according to the Directive 93/42/EEC on Medical Devices.*

**Signed for and on behalf of:**

American Orthodontics  
Sheboygan, WI

**Company Representative:**



Trang Adams / Regulatory Affairs Specialist

