

## Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

**Company Information:**

American Orthodontics  
3524 Washington Avenue  
Sheboygan, WI 53081

**Certificate Number:** 201805-15

**Medical Device Detail:**

**Product/Family Category:** Orthodontic Instruments

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

**Product(s) Tradename(s):**  
See Attachment A

**UMDNS Code:**  
See Attachment A

**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

**Other Standards:** 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:**

**Date:**

3/14/19

Andre Leak / Regulatory Affairs Coordinator

## ATTACHMENT A

Product/Family Category: Orthodontic Instruments

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

<u>Product(s) Tradename(s):</u>	<u>GMDN Code:</u>	<u>UMDNS Code:</u>
Luno™ pliers	33209	16664
Luno™ cutting pliers	33209	16664
Masterline® pliers	33209	16664
Masterline® cutting pliers	33209	16664
AO pliers	33209	16664
Mathieu Needle Holder	33209	16664
Smaha/Hemostat	33209	16664
Single End Explorer	35812	16664
Positive Positioner	31799	16664
Gauge - Dontrix, Boone	31799	16664
Band Contouring Plier	31801	16664
High Heat Bite Stick	31801	16664
Band Seater	31801	16664
Band Pusher	31801	16664
Band/Cement Scaler	31801	16664
Ligature Director	37413	16664
Elastic Placer	62072	16664
Mouth Mirror	31776	16664
T3 Open/Close Instrument	62086	16664
Empower Open/Close Instrument	62086	16664
Alexander Bracket Placement Guide	31799	16664
Bracket Holder	33209	16664
Cap Remover	33209	16664
Distal Twister	33209	16664
Tweezers	none	16664
Spatula	38530	16664
Hex Head Driver	none	16664