

## 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

*Classification is according Medical Device Regulation (MDR) (EU) 2017/745; Annex VIII, Rule 5*

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

See Attachment A

**GMDN Code:**

See Attachment A

**Basic UDI-DI:**

See Attachment A

**CE Authorized Representative:**

MT Promedt Consulting GmbH  
Altenhofstrasse 80  
66386 St. Ingbert  
Germany

**Assessment Details:**

**Route of Directive:** Medical Device Regulation (MDR) (EU) 2017/745

**Standards Applied:**

**Harmonized Standards:** BS EN 1641:2009, EN ISO 10993-1:2009, ISO 13485:2016, EN ISO 14971:2012, EN 1041:2008, EN ISO 15223-1:2016

**Other Standards:** ISO 10993-1:2018, ISO 7405:2018, ISO 15223-2:2010, IEC 62366-1:2015

**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 General Safety and performance Requirements under Medical Device Regulation (MDR) (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer.*

**Signed for and on behalf of:**

American Orthodontics  
Sheboygan, WI

**Company Representative:**

  
Frederick Guesneau / Manager Quality and Regulatory Affairs

**Date:**

May 26<sup>th</sup>, 2021





**AMERICAN  
ORTHODONTICS**

**ATTACHMENT A**

FORM: FM-RA-100.1  
REV: 09 (05/24/2021)

Product/Family Category: Orthodontic Instruments

Classification: Class I

*Classification is according Medical Device Regulation (MDR) (EU) 2017/745; Annex VIII, Rule 5*

<u>Product(s) Tradename(s):</u>	<u>GMDN Code:</u>	<u>Basic UDI-DI:</u>
Cap Remover	33209	0190746000038Q9
Bracket Remover (Luno® Empower Clear / Radiance Bracket Debond)	33209	0190746000038Q9
Dental Explorer ( <i>Single ended explorer</i> )	35812	0190746000030PR
Dental Mirror Stainless Steel	31776	0190746000031PT
Force Gauge ( <i>Dontrix gauge</i> )	31799	0190746000032PV
Hex Head Driver & Accessories	33968	0190746000038Q9
Ligature Pliers ( <i>Coon style ligature tying pliers</i> )	33209	0190746000038Q9
Orthodontic Bracket Height Gage ( <i>Alexander placement guide, Boon Gauge</i> )	31799	0190746000032PV
Orthodontic Ligature Director ( <i>Ligature director, Speedo Ligature Director, Luno wire seater double ended</i> )	37413	0190746000033PX
Orthodontic Metal Band Pusher ( <i>band contouring pliers, high heat bite stick, mallet handled band pusher, double ended band seater, band seating pliers</i> )	31801	0190746000034PZ
Orthodontic Pliers ( <i>Masterline™, Luno™, AO branded</i> )	33209	0190746000035Q3
Self Ligating Orthodontic Bracket Tool ( <i>Luno™ Iconix SL opening tool/wire seater</i> )	62086	0190746000036Q5
Spatula ( <i>single ended spatula, DB adhesive remover double ended</i> )	38530	0190746000037Q7
Tweezers ( <i>College tweezers, Perry Dressing, Bracket holders, &amp; Tube holders, Positive Positioner</i> )	33209	0190746000038Q9
Wire Bender ( <i>Distal Twister</i> )	37413	0190746000038Q9