

## Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

**Company Information:**

American Orthodontics  
3524 Washington Avenue  
Sheboygan, WI 53081

**Certificate Number:** 201805 -01

**Medical Device Detail:**

**Product/Family Category:** Brackets and Bondable Devices

**Classification:** Class IIa *per Rule # 5*

*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:**

**Notified Body:** PCBC Warsaw, Poland

**CE Certificate #:** 1434-MDD-457/2019

**Notified Body #:** 1434

**Issue Date:** 08/29/19

**Route of Directive:** Annex II

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

**Standards Applied:**

**Harmonized Standards:** BS EN 1641:2009, EN ISO 10993-1:2009, EN ISO 10993-3:2014, EN ISO 10993-5:2009, BS EN ISO 10993-11:2018, ISO 13485:2016, EN ISO 14971:2012, EN 1041:2008, EN ISO 15223-1:2016

**Other Standards:** ISO 10993-1:2018, BS EN ISO 10993-10:2013, ISO 7405:2018, ISO 20795-2:2013, ISO 27020:2019, 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 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:**

  
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Frederick Guésneau / Manager Regulatory Affairs and Quality

Date:

10-13-20

## ATTACHMENT A

Product/Family Category: Brackets and Bondable Devices

Classification: Class IIa *per Rule # 5*

*Classification is according Directive 93/42/EEC; Annex IX*

<u>Product(s) Tradename(s):</u>	<u>GMDN Code</u>	<u>UMDNS Code:</u>
Custom Rx (SS brackets)	46581	16360
Empower® 2	46581	16360
Forever Gold™ 24K	46581	16360
Iconix™	46581	16360
LP® Low Profile	46581	16360
Master Series™	46581	16360
Mini Master Series™	46581	16360
Mini Standard Edgewise	46581	16360
Mini Tweed	46581	16360
Silkon Plus™	46582	16360
Empower Clear®	58818	16360
Radiance Plus®	58937	16360
Orthodontic Space Maintainer	31754	--
Bondable Retainer ( <i>and Stainless Steel Flat Braided Lingual Retainer</i> )	35310	--
Ball Hooks	none	12028
Bite Blocks	none	10405
Buttons (Stainless Steel)	none	12028
Coil Eyelet	none	12028
Eyelets	none	12028
Tongue Director	none	12028