

## Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

**Company Information:**

American Orthodontics  
3524 Washington Avenue  
Sheboygan, WI 53081

**Certificate Number:** 201805 -16

**Medical Device Detail:**

**Product/Family Category:** Bands and Attachments

**Classification:** Class IIa *per Rule # 5, 3rd 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:**

**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 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:**

Frederick Guesneau / Manager Regulatory Affairs and Quality

Date: 10-21-2020



FORM: FM-RA-100.1

REV: 08 (02/12/2018)

## ATTACHMENT A

Product/Family Category: Brackets

Classification: Class IIa *per Rule # 5, 3rd indent*

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

<u>Product(s) Tradename(s):</u>	GMDN Code	UMDNS Code
Contoured	38734	--
Anteriors	38734	--
MR	38734	--
MR1	38734	--
MR2	38734	--
MRX Bands	38734	--
Mini Skirt™ Crowns	38734	--
Rollo™ Bands	38734	--
Cleats	none	12028
Elastic Lugs	none	12028
Lingual Sheaths	none	16199