

## Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

**Company Information:**

American Orthodontics  
3524 Washington Avenue  
Sheboygan, WI 53081

**Certificate Number:** 201805 -04

**Medical Device Detail:**

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

**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:** UL International (UK) Ltd.

**CE Certificate #:** 840.180522

**Notified Body #:** 0843

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

**Route of Directive:** Annex V

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



**Standards Applied:**

**Harmonized Standards:** EN ISO 13485, IEC 62336, EN ISO 14971, EN 1041, EN ISO 10993-1, 10993-3, 10993-5, 10993-11, EN 980

**Other Standards:** ISO 10993-10, ISO 7405, ISO 10271, ISO 15223-1, ISO 15223-2, ISO 27020, ISO 9333

**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:**

  
Andre Leak / Regulatory Affairs Coordinator

**Date:**

3/13/19



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>	UMDNS Code:	GMDN Code
20/40 Ceramic Brackets™	16360	58937
Eruption Appliance	none	none
Ceramic Buttons	none	none