

## Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

**Company Information:**

American Orthodontics  
3524 Washington Avenue  
Sheboygan, WI 53081

**Certificate Number:** 201805 -10

**Medical Device Detail:**

**Product/Family Category:** Fixed & Functional and Extra-Oral

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

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

Class I *per Rule # 5, 3rd indent*

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

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

See Attachment A

**GMDN Code:**

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-459/2019

**Notified Body #:** 1434

**Issue Date:** 08/29/2019

**Route of Directive:** Annex V

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

**Standards Applied:**

**Harmonized Standards:** EN 1641, ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 7405, ISO 9333

**Other Standards:** ISO 13485, ISO 14971, EN 1041, ISO 15223-1, ISO 15223-2, IEC/ISO 62366-1

**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:**

9/6/19

## ATTACHMENT A

Product/Family Category: Fixed & Functional and Extra-Oral

Classification: Class IIa *per Rule 5*  
*Classification is according Directive 93/42/EEC; Annex IX*

<u>Product(s) Tradename(s):</u>	GMDN Code:	UMDNS Code:
Alexander Lip Bumper	41678	12374
Expansion Screws	41678	12374
Palatal Arches	41678	12374
Quad Helix	41678	12374

Product/Family Category: Fixed & Functional and Extra-Oral

Classification: Class I *per Rule # 5, 3rd indent*  
*Classification is according Directive 93/42/EEC; Annex IX*

<u>Product(s) Tradename(s):</u>	GMDN Code:	UMDNS Code:
Eaglewear Cervical Neck Strap	31757	16191
Eaglewear High Pull Headgear Strap	31757	16191
Eaglewear Slimline High Pull Release Module	31757	16191
Safety Release Spring Module	31757	16191
Protraction Facemask	31757	16191