

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 *per Rule 5, 1st & 2nd indent*
Classification is according Directive 93/42/EEC; Annex IX

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 # (Class IIa products): 1434-MDD-459/2019
Notified Body #: 1434
Issue Date: 08/29/2019
Route of Directive: VII of the Directive 93/42/EEC on Medical Devices



Standards Applied:

Harmonized Standards: EN ISO 13485, IEC 62336, EN ISO 14971, EN 1041

Other Standards: ISO 15223-1, ISO 15223-2

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:

9/9/19

ATTACHMENT A

Product/Family Category: Orthodontic Instruments

Classification: Class I *per Rule 5, 1st & 2nd indent*
Classification is according Directive 93/42/EEC; Annex IX

<u>Product(s) Tradename(s):</u>	<u>GMDN Code:</u>
Bracket Measuring Gauge - Boone Gauge, Alexander Bracket Placement Guide, Positive Positioner	31799
Cap Remover	none
Dental Explorer	35812
Dental Mirror - Plastic Mouth Mirror (disposable)	none
Dental Mirror - Stainless Steel Mouth Mirror (reusable)	31776
Elastic Placer	62072
Force Gauge - Dontrix	none
Hex Head Driver	none
Interproximal Reduction Strips (IPR)	none
Ligature Director	37413
Ligature Pliers	none
Orthodontic Pliers	33209
Orthodontic Metal Band Pusher	31801
Self-Ligating Orthodontic Bracket Tool	62086
Tweezers	none
Wire Benders	none

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

Carbide Bur	16668
Diamond Bur	16670