

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201805 -11

Medical Device Detail:

Product/Family Category: Orthodontic Wires, Springs, & 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

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-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: EN ISO 13485, IEC 62366, EN ISO 14971, EN 1041, EN ISO 10993-1, 10993-3, 10993-5, 10993-11, EN 1641

Other Standards: ISO 10993-10, ISO 7405, ISO 10271, ISO 15223-1, ISO 15223-2, ISO 15841

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: Orthodontic Wires, Springs, & Attachments

Classification: Class IIa *per Rule # 5, 3rd indent*
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<u>Product(s) Tradename(s):</u>	<u>GMDN Code:</u>	<u>UMDNS Code:</u>
<u>Orthodontic Archwires</u>	41397	16204
Tanzo™ Wire		
NT3™ Wire		
Iconix™ Wire		
<u>Orthodontic Wires</u>	16204	16204
Wrap Around Hawley Retainer Wire		
Stainless Steel Retainer Wire		
Ball Retainer Clasps		
Kobayashi Hooks		
Ligature Wire		
Orientation Pin		
<u>Orthodontic Locks - Stops and Hooks</u>	38741	none
Power Hook		
Surgical Hook		
Arch Hook		
Arch Lock		
Crimpable Stop		
Weldable Stop		