

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics Corp
3524 Washington Avenue
Sheboygan, WI 53081, USA

Certificate Number: 201805 -11

Rev 3

Medical Device Detail:

Product/Family Category: Orthodontic Wires, Springs, & Attachments

Classification: Class IIa *per Rule 5*

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-400/2021

Notified Body #: 1434

Issue Date: 05/25/21

Route of Directive: Annex II

Standards Applied:

Harmonized Standards: EN 1641:2009, EN ISO 10993-1:2009, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016

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

Other Standards: ISO 10993-1:2018, ISO 14971:2019, ISO 7405:2018, ISO 27020:2019, IEC 62366-1:2015, ISO 20417:2021

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 Corp
Sheboygan, WI, USA

Date of Conformity Assessment:

May 25th, 2021

Company Representative:


Frederiek Guesneau / Manager Quality and Regulatory Affairs



ATTACHMENT A

Product/Family Category: Orthodontic Wires, Springs, & Attachments

Classification: Class IIa *per Rule 5*

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

<u>Product(s) Tradename(s):</u>	<u>GMDN Code:</u>	<u>UMDNS Code:</u>
<u>Orthodontic Archwires</u>	41397	16204
<i>Tanzo™ Wire</i>		
<i>NT3™ Wire</i>		
<i>Iconix® Wire</i>		
<i>Wrap Around Hawley Retainer Wire</i>		
<u>Orthodontic Wires</u>	16204	16204
<i>Retainer Wire</i>		
<i>Stainless Steel Retainer Wire</i>		
<i>Ball Retainer Clasps</i>		
<u>Orthodontic Locks - Stops and Hooks</u>	38741	12028
<i>Power Hook</i>		
<i>Surgical Hook</i>		
<i>Arch Hook</i>		
<i>Arch Lock</i>		
<i>Crimpable Stop</i>		
<i>Weldable Stop</i>		
<u>Orthodontic Spring</u>	31797	16204
<i>Diastema</i>		
<i>ART Auxiliary Spring</i>		
<i>Separating Spring</i>		
<u>Orthodontic Archwire/Bracket Ligature</u>	41677	16190
<i>Ligature Wire</i>		