

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

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:



ATTACHMENT A

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

Classification: Class IIa *per Rule # 5, 3rd indent*
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
Therma-Ti® Lite Wire		
Tritanium™ Wire		
Superelastic Titanium Memory Wire		
Gold Coated Wire		
Gold Tone Wire		
Beta Titanium Wire		
Stainless Steel Wire		
Stainless Steel Multi-Strand Wire		
Multiphase Blue Chromium Cobalt Wire		
<u>Orthodontic Springs</u>	31797	none
Nickel Titanium Springs		
Nickel Titanium Memory Springs		
<ul style="list-style-type: none"> ● Closed Coil Adjustable Force with Eyelet ● Distalizing Springs ● Open Coil Adjustable Force 		
Stainless Steel Springs		
<ul style="list-style-type: none"> ● Diastema Closer Spring 		
Uprighting Spring		
Rotation Spring		
Auxiliary Light Torquing Arch		
Compliance Spring		
Separating Spring		
Kilroy Springs		
Ulysses/Extrusion Spring		
<u>Orthodontic Locks - Stops and Hooks</u>	38741	none
Monkey Hook		
Power Pin		