

# 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 -14

Rev 3

**Medical Device Detail:**

Product/Family Category: Orthodontic Supplies / Accessories

Classification: Class IIa *per Rule 6*

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



Product(s) Tradename(s):

See Attachment A

GMDN 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-401/2021

Notified Body #: 1434

Issue Date: 05/25/2021

Route of Directive: Annex V

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

**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

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.*

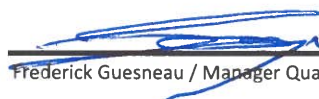
**Signed for and on behalf of:**

American Orthodontics Corp  
Sheboygan, WI, USA

**Date of Conformity Assessment:**

May 25th, 2021

**Company Representative:**



Frederick Guesneau / Manager Quality and Regulatory Affairs



## ATTACHMENT A

Product/Family Category: Orthodontic Supplies / Accessories

Classification: Class IIa *per Rule 6*

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

Product(s) Tradename(s):

*Carbide Debonding Burs*

*Interproximal Diamond Bur*

*Bur Kit*

GMDN Code:

16668

16670

16668