

# Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

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**Company Information:**

American Orthodontics Corporation  
3524 Washington Avenue  
Sheboygan, WI 53081, USA  
SRN: US-MF-000007702  
SRN Importer: NL-IM-000012767

**CE Authorized Representative:**

MT Promedt Consulting GmbH  
Ernst-Heckel-Straße 7  
66386 St. Ingbert  
Germany

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**Scope:**

Appendix A: Instruments  
Appendix B: Supplies  
Appendix C: Elastomerics

**Medical Device Details:**

**Classification:** Class I  
*according to Regulation 2017/745, Annex VIII*

**Products, GMDN/EMDN Codes, and Basic UDI-DI:**  
*See appendices.*

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**Intended Purpose:**

American Orthodontics' devices operate together with other orthodontic devices to apply forces to teeth. Under the supervision of a trained dental professional or orthodontist, this may result in changes to the position of teeth. American Orthodontics' devices are intended and labeled for single-use or single patient use only. American Orthodontics does not condone or support the reuse or reprocessing of single-use devices.

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**Applied Harmonized Standards:** EN ISO  
13485:2016, EN ISO 15223-1:2021, EN ISO  
14971:2019, BS EN 1641:2009

**Applied Other Standards:** ISO 10993-1:2018, ISO  
7405:2018, IEC 62366-1:2015, ISO 20417:2021,  
ISO/TR 20416:2020, ISO 1942:2020

*See appendices for device-specific applied standards.*

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**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 comply with Annex I General Safety and Performance Requirements under Regulation 2017/745 on Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

**Signed for and on behalf of:**


American Orthodontics  
Sheboygan, WI 53081, USA

**Place of Issue:**

American Orthodontics  
Sheboygan, WI 53081, USA

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**Company Representative:**

  
Lindy Couwenhoven / Manager – Product Engineering and Regulatory Affairs

**Date:**

21-JULY-2023



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## Appendix A: Orthodontic Instruments

Device Specific Applied Standards: None

**Scope:**

GMDN Code – 31776: EMDN Code – Q010504:	Dental mirror, reusable	Basic UDI-DI: 0190746000031PT
- Dental Mirror Stainless Steel		
GMDN Code – 31799: EMDN Code – Q010499:	Orthodontic appliance dimension gauge	Basic UDI-DI: 0190746000032PV
- Bracket Placement Guide		
GMDN Code – 37413: EMDN Code – Q010499:	Orthodontic ligature director	Basic UDI-DI: 0190746000033PX
- Orthodontic Ligature Director - Wire Seater		
GMDN Code – 31801: EMDN Code – Q010499:	Orthodontic metal band pusher	Basic UDI-DI: 0190746000034PZ
- Band Pusher - Bite Stick		
GMDN Code – 33209: EMDN Code – Q010499:	Orthodontic Pliers	Basic UDI-DI: 0190746000007PW
- Orthodontic Pliers - Tweezers		
GMDN Code – 62086: EMDN Code – Q010499:	Self-ligating orthodontic bracket open/close tool	Basic UDI-DI: 0190746000036Q5
- Cap Remover		
GMDN Code – 38530: EMDN Code – Q010499:	Dental spatula, reusable	Basic UDI-DI: 0190746000037Q7
- Spatula		
GMDN Code – 44901: EMDN Code – Q010499:	Dental torque wrench	Basic UDI-DI: 0190746000038Q9
- Hex Head Driver and Accessories		



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## Appendix B: Supplies

Device Specific Applied Standards: None

### Scope:

GMDN Code – 31815: EMDN Code – Q019004:	Dental Cotton Roll	Basic UDI-DI: 0190746000050PX
- Disposable Cotton Roll Holder		
GMDN Code – 16350: EMDN Code – Q010503:	Dental Impression Tray, single use	Basic UDI-DI: 0190746000051PX
- Impression Tray		
GMDN Code – 38584: EMDN Code – Q010499:	Bite Registration Rim Wax, plate	Basic UDI-DI: 0190746000052Q3 (VM)
- Ortho Wax Bite (VM)		
- Laminated Bite Wafer (VM)		
GMDN Code – 44858: EMDN Code – Q010499:	Bite Relief Pad	Basic UDI-DI: 0190746000053Q5
- Debond Wafer		
GMDN Code – 58288: EMDN Code – Q010499:	Dental appliance fabrication material, thermoplastic	Basic UDI-DI: 0190746000054Q7
- Atmos		
GMDN Code – 45251: EMDN Code – Q010499:	Orthodontic appliance relief material	Basic UDI-DI: 0190746000055Q9
- Orthodontic Wax		
GMDN Code – 44828: EMDN Code – Q010499:	Dental cheek retractor, professional, reusable	Basic UDI-DI: 0190746000056QB (VM)
- American Cheek Retractor (VM)		
GMDN Code – 13380: EMDN Code – Q010499:	Hand-held Dental Retractor	Basic UDI-DI: 0190746000057QD (VM)
- Clear Photographic Cheek Retractor (VM)		
GMDN Code – 35863: EMDN Code – Q010499:	Alginate dental impression material	Basic UDI-DI: 0190746000058QF (VM)
- Impressa/Chrome		
GMDN Code – 62072: EMDN Code – Q010499:	Orthodontic elastomeric appliance pusher	Basic UDI-DI: 0190746000061Q4
- Elastic Placer		
GMDN Code – 41067: EMDN Code – Q010499:	Orthodontic Chin Cap/Cup	Basic UDI-DI: 0190746000049QE
- Protraction Facemask		



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## Appendix C: Elastomerics

**Device Specific Applied Standards:** None

**Scope:**

<b>GMDN Code – 41677:</b> <b>EMDN Code – Q010406:</b>	<b>Orthodontic archwire/bracket ligature</b>	<b>Basic UDI-DI: 0190746000063Q8</b>
- Clear Rotation Wedges (VM)		