

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

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

Certificate Number: MDR 752691 R000

Scope:

Appendix A: Bondable Devices
Appendix B: Elastomerics
Appendix C: Wires, Springs, and Attachments
Appendix D: Bands and Attachments
Appendix E: Fixed and Functional Devices
Appendix F: Bonding Agents

Medical Device Details:

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

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

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.

CE Authorized Representative:

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

Assessment Details:

Notified Body: BSI Group the Netherlands B.V
CE Certificate #: MDR 752691
Notified Body #: 2797
Issue Date: June 2nd, 2023
Route of Directive: Annex IX, Chapters I and III
Of the Regulation 2017/745 on Medical Devices

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

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

Company Representative:

Lindy Couwenhoven / Manager – Product Engineering and Regulatory Affairs

Date: 21 - JULY - 2023



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Appendix A: Bondable Devices

Device Specific Applied Standards: ISO 27020:2019

Scope:

GMDN Code – 46581: EMDN Code – Q010403:	Orthodontic Brackets, Metal	Basic UDI-DI: 0190746000003PN
- Empower Brackets - Mini Master Series Brackets - Master Series Brackets - Mini Tweed	- LP Low Profile - Forever Gold 24K - Mini Standard Edgewise	- Buttons - Iconix Brackets - Stainless Steel Bracket
GMDN Code – 58937: EMDN Code – Q010403:	Orthodontic Brackets, Ceramic	Basic UDI-DI: 0190746000004PQ Basic UDI-DI: 0190746000001PJ (VM)
- Radiance Plus - 20/40 (VM)	- Ceramic Button	- Ceramic Button (VM)
GMDN Code – 58818: EMDN Code – Q010403:	Self-Ligating Orthodontic Brackets	Basic UDI-DI: 0190746000005PS
- Empower Clear		
GMDN Code – 35310: EMDN Code – Q010499:	Bondable Retainer	Basic UDI-DI: 0190746000009Q2
- Bondable Retainer		
GMDN Code – 62683: EMDN Code – Q010499:	Tongue Director	Basic UDI-DI: 0190746000007PW
- Tongue Director	- Bite Blocks	
GMDN Code – 31759: EMDN Code – Q010403:	Orthodontic Tube	Basic UDI-DI: 01907460000012PP
- Empower Tubes - Mini Master Series Tubes - Master Series Tubes	- iFit - LP - Slim Tube	- Buccal Tubes - Iconix Tubes
GMDN Code – 63223: EMDN Code – Q010499:	Orthodontic Power Arm	Basic UDI-DI: 0190746000008PY Basic UDI-DI: 0190746000002PL (VM)
- UT Hook	- Eyelets	- Hooks



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Appendix B: Elastomerics

Device Specific Applied Standards: ISO 21606:2007

Scope:

GMDN Code – 41677: EMDN Code – Q010406:	Orthodontic Arch Wire/Bracket Ligature	Basic UDI-DI: 0190746000017PZ Basic UDI-DI: 0190746000016PX (VM)
- Orthodontic Ligature	- Orthodontic Ligature (VM)	
GMDN Code – 63708: EMDN Code – Q010404:	Orthodontic Separator	Basic UDI-DI: 0190746000021PQ Basic UDI-DI: 0190746000064QA (VM)
- Separator	- Separator (VM)	
GMDN Code – 62073: EMDN Code – Q010404:	Orthodontic Inter-Bracket Elastic Chain	Basic UDI-DI: 0190746000019Q5
- Elastic Chain		
GMDN Code – 62074: EMDN Code – Q010404:	Orthodontic Inter-Arch Elastic Band	Basic UDI-DI: 0190746000020PN
- The Wildlife Series Elastics	- Sea Life Elastics	
GMDN Code – 65562: EMDN Code – Q010404:	Orthodontic Arch Wire Protection Sleeve	Basic UDI-DI: 0190746000062Q6 (VM)
- Arch Wire Sleeves (VM)		



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Appendix C: Wires, Springs, and Attachments

Device Specific Applied Standards: ISO 15841:2014/AMD 1:2020, ISO 17254:2016+A1:2021, ISO 10271:2020

Scope:

GMDN Code – 41397: EMDN Code – Q010405:	Orthodontic Arch Wires	Basic UDI-DI: 0190746000023PU Basic UDI-DI: 0190746000022PS (VM)
- Iconix - NT3 - Tanzo	- Stainless Steel Wire (VM) - Chromium Cobalt Wire (VM) - Titanium Wire (VM)	- NiTi Wire (VM) - Therma-Ti (VM) - TriTanium (VM)
GMDN Code – 16204: EMDN Code – Q010405:	Orthodontic Wires	Basic UDI-DI: 0190746000006PU (VM)
- Retainer Wire (VM)		
GMDN Code – 41677: EMDN Code – Q010406:	Orthodontic Arch Wire/Bracket Ligature	Basic UDI-DI: 0190746000017PZ Basic UDI-DI: 0190746000016PX (VM)
- Orthodontic Ligature	- Orthodontic Ligature (VM)	
GMDN Code – 31797: EMDN Code – Q010404:	Orthodontic Springs	Basic UDI-DI: 0190746000027Q4 Basic UDI-DI: 0190746000026Q2 (VM)
- ART Spring	- NiTi Springs (VM)	- Stainless Steel Springs (VM)
GMDN Code – 38741: EMDN Code – Q010499:	Orthodontic Locks	Basic UDI-DI: 0190746000028Q6 Basic UDI-DI: 0190746000029Q8 (VM)
- Orthodontic Lock - Orthodontic Lock (VM)	- Arch Lock	- Monkey Hook (VM)
GMDN Code – 63223: EMDN Code – Q010499:	Orthodontic Power Arm	Basic UDI-DI: 0190746000008PY Basic UDI-DI: 0190746000002PL (VM)
- Orthodontic Power Arm	- Orthodontic Power Arm (VM)	



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Appendix D: Bands and Attachments

Device Specific Applied Standards: None

Scope:

GMDN Code – 38734: EMDN Code – Q010402:	Orthodontic Band	Basic UDI-DI: 0190746000039QB
- MR	- Micro	- Orthodontic Bands
- MRX	- Mini Skirt Crowns	- Orthodontic Band Attachments
- Hard Line	- Rollo Bands	- Lingual Sheaths



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Appendix E: Fixed and Functional Devices

Device Specific Applied Standards: ISO 17254:2016, ISO 10271:2020

Scope:

GMDN Code – 65804: EMDN Code – Q010499:	Orthodontic rod-based aligner	Basic UDI-DI: 0190746000045Q6
- Herbst Devices - PowerBar - Jumpers	- Jones Jig - Rapid Molar Intruder	- Quick Fix - PowerScope
GMDN Code – 16204: EMDN Code – Q010499:	Orthodontic wire	Basic UDI-DI: 0190746000024PW
- Lip Bumpers		
GMDN Code – 46493: EMDN Code – Q010499:	Dental occlusal splint, customizable	Basic UDI-DI: 0190746000065QC
- M.A.P. Mini Activator Posturer		
GMDN Code – 64769: EMDN Code – Q010499:	Orthodontic palate expander/teeth aligner, bonded	Basic UDI-DI: 0190746000066QE Basic UDI-DI: 0190746000048QC (VM)
- Jet Devices	- Palatal Arches (VM)	- Quad Helix (VM)



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Appendix F: Bonding Agents

Device Specific Applied Standards: ISO 4049:2019, ISO 29022:2013, ISO 11405:2015

Scope:

GMDN Code – 31750: EMDN Code – Q010407:	Orthodontic Bracket Adhesive	Basic UDI-DI: 0190746000013PR (VM)
- BracePaste Adhesive (VM)		
GMDN Code – 34771: EMDN Code – Q010407:	Dental Unfilled Resin Sealant/Coating	Basic UDI-DI: 0190746000014PT (VM)
- BracePaste Primer (VM)		
GMDN Code – 36153: EMDN Code – Q010407:	Dental Etching Solution	Basic UDI-DI: 0190746000015PV (VM)
- Acid Etchant (VM)		