



American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

www.americanortho.com

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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

CE Authorized Representative:

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

Scope:

Appendix A: Instruments
Appendix B: Supplies

Medical Device Details:

Classification: Class I
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.

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:


Mike Hetue / Manager – Product Engineering and Regulatory Affairs

Date: 24-FEB-2026





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Appendix A: Orthodontic Instruments

Device Specific Applied Standards: None

Scope:

EMDN Q010499: ORTHODONTIC DEVICES – OTHER	
GMDN 31799: ORTHODONTIC APPLIANCE DIMENSION GAUGE	
BRAND NAME	BASIC UDI-DI
Bracket Placement Guide	01907460000183E5
GMDN 31801: ORTHODONTIC METAL BAND PUSHER	
BRAND NAME	BASIC UDI-DI
Band Pusher	01907460000181DZ
Bite Stick	01907460000182E3
GMDN 33209: ORTHODONTIC PLIERS	
BRAND NAME	BASIC UDI-DI
Luno Debonding Instrument	01907460000187ED
Luno Pliers	01907460000189EH
Tweezers	01907460000192E6
GMDN 37413: ORTHODONTIC LIGATURE DIRECTOR	
BRAND NAME	BASIC UDI-DI
Hand Instrument	01907460000185E9
Luno Hand Instrument	01907460000231DP
GMDN 38530: DENTAL SPATULA, REUSABLE	
BRAND NAME	BASIC UDI-DI
Spatula	01907460000190E2
GMDN 44901: DENTAL TORQUE WRENCH	
BRAND NAME	BASIC UDI-DI
Hex Head Instrument	01907460000186EB
GMDN 62086: SELF-LIGATING ORTHODONTIC BRACKET OPEN/CLOSE TOOL	
BRAND NAME	BASIC UDI-DI
Cap Remover	01907460000184E7
Luno Empower Instrument	01907460000188EF
EMDN Q010504: DENTISTRY MIRRORS AND STYLETS	
GMDN 31776: DENTAL MIRROR, REUSABLE	
BRAND NAME	BASIC UDI-DI
Stainless Steel Mouth Mirror	01907460000191E4

Appendix B: Supplies

Device Specific Applied Standards: None

Scope:

EMDN Q010499: ORTHODONTIC DEVICES – OTHER	
GMDN 13380: HAND-HELD DENTAL RETRACTOR	
BRAND NAME	BASIC UDI-DI
Clear Cheek Retractor	01907460000195EC
GMDN 35863: ALGINATE DENTAL IMPRESSION MATERIAL	
BRAND NAME	BASIC UDI-DI
Impressa/Chrome	01907460000199EL
GMDN 38584: BITE REGISTRATION RIM WAX, PLATE	
BRAND NAME	BASIC UDI-DI
Laminated Bite Wafer	01907460000201DE
Ortho Wax Bite	01907460000202DG
GMDN 41067: ORTHODONTIC CHIN CAP/CUP	
BRAND NAME	BASIC UDI-DI
Protraction Facemask	01907460000204DL
GMDN 44828: DENTAL CHEEK RETRACTOR, PROFESSIONAL, REUSABLE	
BRAND NAME	BASIC UDI-DI
American Cheek Retractor	01907460000193E8
GMDN 44858: BITE RELIEF PAD	
BRAND NAME	BASIC UDI-DI
Debond Wafer	01907460000197EG
GMDN 45251: ORTHODONTIC APPLIANCE RELIEF MATERIAL	
BRAND NAME	BASIC UDI-DI
Orthodontic Wax	01907460000203DJ
GMDN 58288: DENTAL APPLIANCE FABRICATION MATERIAL, THERMOPLASTIC	
BRAND NAME	BASIC UDI-DI
Atmos	01907460000194EA
Vero	01907460000234DV
GMDN 62072: ORTHODONTIC ELASTOMERIC APPLIANCE PUSHER	
BRAND NAME	BASIC UDI-DI
Elastic Placer	01907460000198EJ
EMDN Q010503: IMPRESSION MATERIAL TRAYS, SINGLE-USE	
GMDN 16350: DENTAL IMPRESSION TRAY, SINGLE USE	
BRAND NAME	BASIC UDI-DI
Impression Tray	01907460000200DC
EMDN Q019004: DENTAL COTTON ROLLS	
GMDN 31815: DENTAL COTTON ROLL	
BRAND NAME	BASIC UDI-DI
Cotton Roll Holder	01907460000196EE