



Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

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

Certificate Number: 201805-10

Rev 5

Medical Device Detail:

Product/Family Category: Orthodontic Instruments

Classification: Class I

Classification is according Medical Device Regulation (MDR) (EU) 2017/745; Annex VIII, Rule 5

Product(s) Tradename(s):

See Attachment A

GMDN Code:

See Attachment A

Basic UDI-DI:

See Attachment A

CE Authorized Representative:

MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert
Germany

Assessment Details:

Route of Directive: Medical Device Regulation (MDR) (EU) 2017/745



Standards Applied:

Harmonized Standards: EN ISO 13485:2016, EN ISO 15223-1:2021

Other Standards: ISO 10993-1:2018, ISO 7405:2018, IEC 62366-1:2015, ISO 14971:2019, ISO 20417:2021, ISO 15223-1:2016, BS EN 1041:2008
ISO 14971:2012, BS 1041:2008, ISO 15223-1:2016

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 General Safety and performance Requirements under Medical Device Regulation (MDR) (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer.

Signed for and on behalf of:

American Orthodontics
Sheboygan, WI, USA

Date of Conformity Assessment:

May 25th, 2021

Company Representative:


Frederick Guesnard / Manager Quality and Regulatory Affairs



ATTACHMENT A

Product/Family Category: Orthodontic Instruments

Classification: Class I

Classification is according Medical Device Regulation (MDR) (EU) 2017/745; Annex VIII, Rule 5

Product(s) Tradename(s):

GMDN Code:

Basic UDI-DI:

Bracket Remover (Luno® Empower Clear / Radiance Bracket Debond)	33209	0190746000038Q9
Dental Mirror Stainless Steel	31776	0190746000031PT
Hex Head Driver & Accessories	33968	0190746000038Q9
Ligature Pliers (<i>Coon Style Ligature Tying pliers, Force Module Separator</i>)	33209	0190746000038Q9
Orthodontic Bracket Height Gage (<i>Alexander placement guide, Boon Gauge</i>)	31799	0190746000032PV
Orthodontic Ligature Director (<i>Ligature director, Speedo Ligature Director, Luno wire seater double ended</i>)	37413	0190746000033PX
Orthodontic Metal Band Pusher (<i>band contouring pliers, high heat bite stick, mallet handled band pusher, band seating pliers</i>)	31801	0190746000034PZ
Orthodontic Pliers (<i>Masterline™, Luno™, AO branded</i>)	33209	0190746000035Q3
Self Ligating Orthodontic Bracket Tool (<i>Luno™ Iconix SL opening tool/wire seater</i>)	62086	0190746000036Q5
Spatula (<i>single ended spatula</i>)	38530	0190746000037Q7
Tweezers (<i>College tweezers, Perry Dressing, Bracket holders, & Tube holders</i>)	33209	0190746000038Q9
Wire Bender (<i>Distal Twister</i>)	37413	0190746000038Q9

