

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201805-15

Medical Device Detail:

Product/Family Category: Orthodontic Instruments

Classification: Class I *per Rule 5*

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 # (Class IIa products): 1434-MDD-259/2020

Notified Body #: 1434

Issue Date: 06/23/2020

Route of Directive: VII of the Directive 93/42/EEC on Medical Devices

Standards Applied:

Harmonized Standards: BS EN 1641:2009, EN ISO 10993-1:2009, EN ISO 10993-3:2014, EN ISO 10993-5:2009, ISO 13485:2016, EN ISO 14971:2012, EN 1041:2008, EN ISO 15223-1:2016

Other Standards: ISO 10993-1:2018, BS EN ISO 10993-10:2013, ISO 7405:2018, ISO 15223-2:2010, IEC 62366-1:2015

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
Sheboygan, WI

Company Representative:

Date: 16-13-20

Frederick Guesneau / Manager Regulatory Affairs and Quality



**AMERICAN
ORTHODONTICS**

ATTACHMENT A

FORM: FM-RA-100.1
REV: 08 (02/12/2018)

Product/Family Category: Orthodontic Instruments

Classification: Class I *per Rule 5*

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

<u>Product(s) Tradename(s):</u>	GMDN Code:
Cap Remover	33209
Dental Explorer (<i>Single ended explorer</i>)	62072
Dental Mirror Stainless Steel (<i>reusable</i>)	31776
Elastics Placer	62072
Force Gauge (Dontrix)	31799
Hex Head Driver & Accessories	none
Ligature Pliers (<i>Coon style ligature tying pliers</i>)	none
Orthodontic Bracket Measuring Gage (<i>Alexander placement guide, Boon Gauge, & Positive Positioner</i>)	31799
Orthodontic Ligature Director (<i>Ligature director, Speedo Ligature Director</i>)	37413
Orthodontic Metal Band Pusher (<i>high heat bite stick, mallet handled band pusher, double ended band seater</i>)	31801
Orthodontic Pliers (<i>Masterline™, Luno™, AO branded</i>)	33209
Self Ligating Orthodontic Bracket Tool (<i>Luno™ Iconix SL opening tool/wire seater</i>)	62086
Spatula	38530
Tweezers (<i>College tweezers, Perry Dressing, Bracket holders, & Tube holders</i>)	none
Wire Bender (<i>Distal Twister</i>)	33209
Luno Empower Clear / Radiance Bracket Debond	none