



Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics Corp
3524 Washington Avenue
Sheboygan, WI 53081, USA

Certificate Number: 201805 -08

Rev 3



Medical Device Detail:

Product/Family Category: Fixed & Functional and Extra-Oral

Classification: Class IIa *per Rule 5*

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

Class I *per Rule 5*

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

Product(s) Tradename(s):

See Attachment A

GMDN Code:

See Attachment A

UMDNS 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 #: 1434-MDD-400/2021

Notified Body #: 1434

Issue Date: 05/25/21

Route of Directive: Annex II

of the Directive 93/42/EEC on Medical Devices.

Standards Applied:

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

Other Standards: ISO 10993-1:2018, ISO 14971:2019, ISO 7405:2018, ISO 27020:2019, 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 Corp
Sheboygan, WI, USA

Date of Conformity Assessment:

May 25th, 2021

Company Representative:


Frederick Guesneau / Manager Quality and Regulatory Affairs



ATTACHMENT A

Product/Family Category: Fixed & Functional and Extra-Oral

Classification: Class IIa *per Rule 5*

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

<u>Product(s) Tradename(s):</u>	GMDN Code:	UMDNS Code:
Distal Jet	64769	12374
Spring Jet	64769	12374
Uprighter Jet	64769	12374
Mesial Jet	64769	12374
Jumpers	65804	12374
· <i>Gentle Jumper</i>		
· <i>Jasper Jumper</i>		
Hanks Telescoping Herbst®	65804	12374
Herbst™ Appliance	65804	12374
Jones Jig™	65804	12374
M.A.P. Mini Activator Posturer	46493	12374
Lip Bumper	16204	12374
· <i>Korn Lip Bumper</i>		
· <i>Lip Bumper</i>		
Miniscope™ Telescoping Herbst®	65804	12374
Powerscope™ 2	65804	12374
Quick Fix	65804	12374
Rapid Molar Intruder	65804	12374

Product/Family Category: Fixed & Functional and Extra-Oral

Classification: Class I *per Rule 5*

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

<u>Product(s) Tradename(s):</u>	GMDN Code:	UMDNS Code:
YC3 Shield	46493	12374