

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201805 -10**Medical Device Detail:****Product/Family Category:** Fixed & Functional and Extra-Oral**Classification:** Class IIa *per Rule 5**Classification is according Directive 93/42/EEC; Annex IX*Class I *per Rule # 5, 3rd indent**Classification is according Directive 93/42/EEC; Annex IX***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-457/2019**Notified Body #:** 1434**Issue Date:** 08/29/19**Route of Directive:** Annex II*of the Directive 93/42/EEC on Medical Devices.***Standards Applied:****Harmonized Standards:** EN 1641, ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 7405, ISO 9333**Other Standards:** ISO 13485, ISO 14971, EN 1041, ISO 15223-1, ISO 15223-2, IEC/ISO 62366-1**Declaration statement:**

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:

Andre Leak / Regulatory Affairs Coordinator

Date:

9/6/19



ATTACHMENT A

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

Classification: Class IIa *per Rule 5*

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

<u>Product(s) Tradename(s):</u>	<u>GMDN Code:</u>	<u>UMDNS Code:</u>
Jones Jig™	41678	12374
Distal Jet	41678	12374
Hanks Telescoping Herbst®	41678	12374
Herbst™ Appliance	41678	12374
Miniscope™ Telescoping Herbst®	41678	12374
Jasper Jumper	41678	12374
Gentle Jumper	41678	12374
Powerscope™ 2	41678	12374
Korn Lip Bumper	41678	12374
Lip Bumper	41678	12374
Quick Fix	41678	12374
Mesial Jet	41678	12374
Spring Jet	41678	12374
Uprighter Jet	41678	12374
Korn Mini-Activator Posturer (M.A.P)	41678	12374
Rapid Molar Intruder	41678	12374
300 Series Face Bows	40468	16192

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

Classification: Class I *per Rule # 5, 3rd indent*

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

<u>Product(s) Tradename(s):</u>	<u>GMDN Code:</u>	<u>UMDNS Code:</u>
YC3 Shield	41678	12374
Ortho Band Neck Straps with Safety Chain	31757	16191