

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

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: UL International (UK) Ltd.

CE Certificate #: 840.180522

Notified Body #: 0843

Issue Date: 05/22/18

Route of Directive: Annex V

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

Standards Applied:

Harmonized Standards: EN ISO 13485, IEC 62336-1, EN ISO 14971, EN 1041, EN ISO 10993-1, 10993-3, 10993-5, 10993-11, EN 980

Other Standards: ISO 10993-10, ISO 7405, ISO 10271, ISO 15223-1, ISO 15223-2, ISO 9333

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: 5/8/19

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>
Alexander Lip Bumper	41678	12374
Expansion Screws	41678	12374
Palatal Arches	41678	12374
Quad Helix	41678	12374
Eaglewear Slimline High Pull Release Module	31757	16191
Safety Release Spring Module	31757	16191
Eaglewear Cervical Neck Strap	31757	16191
Eaglewear High Pull Headgear Strap	31757	16191
Protraction Facemask	31757	16191