

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201805 -12

Medical Device Detail:

Product/Family Category: Elastomerics

Classification: Class IIa *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, ISO7405, ISO 21606

Other Standards: ISO 13485, ISO 14971, ISO 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:

Date:

9/6/19

Andre Leak / Regulatory Affairs Coordinator

**AO AMERICAN
ORTHODONTICS
ATTACHMENT A**

FORM: FM-RA-100.1

REV: 08 (02/12/18)

Product/Family Category: Elastomerics

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<u>Product(s) Tradename(s):</u>	<u>GMDN Code:</u>	<u>UMDNS Code:</u>
The Wildlife Series™	62074	16190
Sea Life Non Latex	62074	16190
Colored Chain	62073	16190
Colored Ligatures	41677	16190
Memory Chain	62073	16190
X-Ring Separators	63708	13540