

## 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:** UL International (UK) Ltd.

**CE Certificate #:** 840.180522

**Notified Body #:** 0843

**Issue Date:** 05/22/18

**Route of Directive:** Annex II

*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

**Other Standards:** ISO 10993-10, ISO 7405, ISO 15223-1, ISO 15223-2, ISO 21606

**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

**AO AMERICAN**  
ORTHODONTICS  
**ATTACHMENT A**

FORM: FM-RA-100.1

REV: 08 (02/12/18)

Product/Family Category: Elastomerics

Classification: Class IIa *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>
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