

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 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

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

ATTACHMENT A

Product/Family Category: Elastomerics

Classification: Class IIa *per Rule 5, 3rd indent*

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<u>Product(s) Tradename(s):</u>	<u>GMDN Code:</u>	<u>UMDNS Code:</u>
Arch Wire Sleeve	41677	14457
Clear Rotation Wedges	45007	13540
EZ Tie Tubing	41677	14457
Plastic Tie	41677	16190
White Separators	63708	13540
Blue Radio Opaque Separators	63708	13540