

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201805 -13

Medical Device Detail:

Product/Family Category: Orthodontic Supplies

Classification: Class I *per Rule 5, 1st & 2nd indent*
Classification is according Directive 93/42/EEC; Annex IX

Product(s) Tradename(s):

See Attachment A

GMDN Code:

See Attachment A

CE Authorized Representative:

MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert
Germany

Assessment Details:

Route of Directive: VII of the Directive 93/42/EEC on Medical Devices

Standards Applied:

Harmonized Standards: EN ISO 13485, IEC 62336, EN ISO 14971, EN 1041, EN 980

Other Standards: ISO 15223-1, ISO 15223-2

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:

9/30/19



ATTACHMENT A

Product/Family Category: Orthodontic Supplies

Classification: Class I *per Rule 5, 1st & 2nd indent*
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<u>Product(s) Tradename(s):</u>	<u>GMDN Code:</u>
Applicator Tips	33721
Cheek Retractors (American)	44828
Cheek Retractors (Clear)	44828
Cotton Roll Holders	31815
Debond Wafers	38584
Dental Impression Tray	16350
Impressa/Chrome™ Alginate	35863
Impressa/Sure™	35863
Laminated Bite Wafers	38584
NOLA Dry Field System	44828
Ortho Wax Bites	45251
Orthodontic Silicone Wax	45251
Orthodontic Wax	45251
Photographic Mirror	31776
Toothbrushes	31817