



Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081, USA
SRN: US-MF-000007702
SRN Importer: NL-IM-000012767

Certificate Number: 201805 -13

Rev 4

Medical Device Detail:

Product/Family Category: Orthodontic Supplies

Classification: Class I

Classification is according Medical Device Regulation (MDR) (EU) 2017/745; Annex VIII, Rule 5

Product(s) Tradename(s):

See Attachment A

GMDN Code:

See Attachment A

Basic UDI-DI:

See Attachment A

CE Authorized Representative:

MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert
Germany

Assessment Details:

Route of Directive: Medical Device Regulation (MDR) (EU) 2017/745

Standards Applied:

Harmonized Standards: EN ISO 13485:2016, EN ISO 15223-1:2021

Other Standards: ISO 10993-1:2018, ISO 7405:2018, IEC 62366-1:2015, ISO 14971:2019, ISO 20417:2021, ISO 15223-1:2016, BS EN 1041:2008



Declaration statement:

This Declaration of Conformity is issued under the sole responsibility of American Orthodontics. 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 General Safety and performance Requirements under Medical Device Regulation (MDR) (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer.

Signed for and on behalf of:

American Orthodontics Corp
Sheboygan, WI, USA

Date of Conformity Assessment:

May 25th, 2021

Company Representative:


Frederick Guesneau / Manager Quality and Regulatory Affairs



ATTACHMENT A

Product/Family Category: Orthodontic Supplies

Classification: Class I *per Rule 5*

Classification is according Medical Device Regulation (MDR) (EU) 2017/745; Annex VIII

<u>Product(s) Tradename(s):</u>	<u>GMDN Code:</u>	<u>Basic UDI-DI:</u>
<i>Cheek Retractors (American)</i>	44828	0190746000056QB
<i>Cheek Retractors (Clear)</i>	13380	0190746000057QD
<i>Impressa/Chrome™ Alginate</i>	35863	0190746000058QF
<i>Laminated Bite Wafers</i>	38584	0190746000052Q3
<i>Ortho Wax Bites</i>	38584	0190746000052Q3
<i>Orthodontic Wax</i>	45251	0190746000055Q9
<i>atmos® Thermoforming Plastic</i>	58288	0190746000054Q7
<i>Cotton Roll Holders</i>	31815	0190746000050PX
<i>Debond Wafers</i>	44858	0190746000053Q5
<i>Dental Impression Tray</i>	16350	0190746000051PX