

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics Corp
3524 Washington Avenue
Sheboygan, WI 53081, USA

Certificate Number:

201805 -17

Rev 3

SRN: US-MF-000007702

Medical Device Detail:

Product/Family Category: Elastomerics

Classifications: Class I per Rule 5

Classification is according to Regulation 2017/745; Annex VIII



Product(s) Tradename(s):

See Attachment A

GMDN Code

See Attachment A

UMDNS Code

See Attachment A

Basic UDI-DI

See Attachment A

CE Authorized Representative:

MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert
Germany

Standards Applied:

Harmonized Standards:

EN 1641:2009, EN ISO 10993-1:2009, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016

Other Standards:

ISO 10993-1:2018, ISO 14971:2019, ISO 7405:2018, ISO 27020:2019, IEC 62366-1:2015, ISO 20417:2021

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 Regulation 2017/745 on Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Signed for and on behalf of:

American Orthodontics Corp
Sheboygan, WI 53081, USA

Date of Conformity Assessment:

May 25th, 2021

Company Representative:


Frederick Guesneau / Manager Regulatory Affairs and Quality



ATTACHMENT A

Product/Family Category: Elastomerics

Classification: Class I *per Rule 5*

Classification is according to Regulation 2017/745; Annex VIII

Product(s) Tradename(s):

Clear Rotation Wedges

GMDN Code

41677

UMDNS Code

13540

Basic UDI-DI

0190746000018Q3