

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 -07

Rev 3

Medical Device Detail:

Product/Family Category: Elastomerics

Classifications: Class I per Rule 5

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

Class IIa per Rule 5

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: PCBC Warsaw, Poland

CE Certificate #: 1434-MDD-401/2021

Notified Body #: 1434

Issue Date: 05/25/2021

Route of Directive: Annex V

of the Directive 93/42/EEC on Medical Devices.

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 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 Corp
Sheboygan, WI, USA

Date of Conformity Assessment:

May 25th, 2021

Company Representative:


Frederick Guesneau / Manager Quality and Regulatory Affairs

AO AMERICAN
ORTHODONTICS
ATTACHMENT A

Product/Family Category: Elastomerics

Classification: Class I *per Rule 5*

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

Product(s) Tradename(s):

GMDN Code:

UMDNS Code:

Clear Rotation Wedges

41677

13540

Product/Family Category: Elastomerics

Classification: Class IIa *per Rule 5*

Classification is according Directive 93/42/EEC; Annex IX

Product(s) Tradename(s):

GMDN Code

UMDNS Code

Arch Wire Sleeve

65562

16190

Blue Radio Opaque Separators (loose)

63708

13540

EZ Tie Tubing

41677

16190

Plastic Tie

41677

16190

Textured Thread

41677

16190