

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201805 -16

Medical Device Detail:

Product/Family Category: Fixed & Functional and Extra-Oral

Classification: Class IIa *per Rule 5*

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

Class I *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-259/2020

Notified Body #: 1434

Issue Date: 06/23/2020

Route of Directive: Annex V

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

Standards Applied:

Harmonized Standards: BS EN 1641:2009, EN ISO 10993-1:2009, EN ISO 10993-3:2014, EN ISO 10993-5:2009, BS EN ISO 10993-11:2018, ISO 13485:2016, EN ISO 14971:2012, EN 1041:2008, EN ISO 15223-1:2016

Other Standards:

ISO 10993-1:2018, BS EN ISO 10993-10:2013, ISO 7405:2018, ISO 15223-2:2010, IEC 62366-1:2015

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
Sheboygan, WI

Company Representative:


Frederick Guesneau / Manager Regulatory Affairs and Quality

Date: 10-14-20



FORM: FM-RA-100.1
REV: 08 (02/12/2018)

ATTACHMENT A

Product/Family Category: Fixed & Functional and Extra-Oral

Classification: Class IIa *per Rule 5*

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

Product(s) Tradename(s):

Palatal Arches

Quad Helix

GMDN Code:

41678

41678

UMDNS Code:

12374

12374

Product/Family Category: Fixed & Functional and Extra-Oral

Classification: Class I *per Rule 5*

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

Product(s) Tradename(s):

Protraction Facemask

GMDN Code:

31757

UMDNS Code:

16191