

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081 USA

Certificate Number: 201805 -06

SRN: US-MF-000007702



Medical Device Detail:

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

Classification: Class I *per Rule 5*

Classification is according to Regulation 2017/745; Annex VIII

<u>Product(s) Tradename(s):</u>	GMDN Code	UMDNS Code	Basic UDI-DI
See Attachment A	See Attachment A	See Attachment A	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 10993-3:2014, EN ISO 10993-5:2009, 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, 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 General Safety and Performance Requirements under Regulation 2017/745 on Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

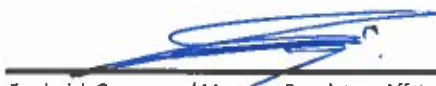
Signed for and on behalf of:

American Orthodontics
Sheboygan, WI 53081 USA

Place of Issue:

American Orthodontics
Sheboygan, WI 53081 USA

Company Representative:


Frederick Guesneau / Manager Regulatory Affairs and Quality

Date: Aug 6th 2021



ATTACHMENT A

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

Classification: Class I *per Rule 5*

Classification is according to Regulation 2017/745; Annex VIII

<u>Product(s) Tradename(s):</u>	GMDN Code	UMDNS Code	Basic UDI-DI
YC3 Shield	45007	13540	0190746000046Q8