

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201805 -05

Medical Device Detail:

Product/Family Category: Buccal Tubes

Classification: 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

CE Authorized Representative:

MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert
Germany

Assessment Details:

Notified Body: PCBC Warsaw, Poland

CE Certificate #: 1434-MDD-457/2019

Notified Body #: 1434

Issue Date: 08/29/19

Route of Directive: Annex II

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

Standards Applied:

Harmonized Standards: EN 1041:2008, 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 ISO 15223-1:2016

Other Standards: ISO 10993-10:2013, IEC 62366-1:2015, ISO 15223-2:2010, EN ISO 27020:2019, ISO 7405:2018

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:

9-24-20



ATTACHMENT A

Product/Family Category: Buccal Tubes

Classification: Class IIa *per Rule # 5*

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

<u>Product(s) Tradename(s):</u>	<u>GMDN Code:</u>	<u>UMDNS Code:</u>
AO Stainless Steel Buccal Tubes	31759	16199
Auxiliary Hook	none	12028
Empower® 2	31759	16199
iFit®	31759	16199
LP® Low Profile	31759	16199
Master Series™	31759	16199
Mini Master Series™	31759	16199
Slim Tube™	31759	16199