

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, 3rd indent*
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 1641, ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 7405, ISO 27020, ISO 7405, ISO 9333

Other Standards: ISO 13485, ISO 14971, EN 1041, ISO 15223-1, ISO 15223-2, IEC/ISO 62366-1

Declaration statement:

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:

Andre Leak / Regulatory Affairs Coordinator

Date:

9/6/19



ATTACHMENT A

Product/Family Category: Buccal Tubes

Classification: Class IIa *per Rule # 5, 3rd indent*
Classification is according Directive 93/42/EEC; Annex IX

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