

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: UL International (UK) Ltd.

CE Certificate #: 840.180522

Notified Body #: 0843

Issue Date: 05/22/18

Route of Directive: Annex II

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

Standards Applied:

Harmonized Standards: EN ISO 13485, IEC 62336, EN ISO 14971, EN 1041, EN ISO 10993-1, 10993-3, 10993-5, 10993-11

Other Standards: ISO 15223-1, ISO 15223-2

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:

3/14/19



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>
Empower® 2	31759
Mini Master Series™	31759
Master Series™	31759
iFit®	31759
LP® Low Profile	31759
Slim Tube™	31759
AO Stainless Steel Buccal Tubes	31759
Auxiliary Hook	31759