AMERICAN ORTHODONTICS

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201805 -05
Certificate Issue Date: 05/22/18
Certificate Expiry Date: 11/20/22
This certificate is valid until Expiry Date listed above.

Medical Device Detail:

Product/Family Category: Buccal Tubes

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

Intended Use: American Orthodontics' products are used for the orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist.

Product(s) Tradename(s):

Empower®	Piggyback Tubes	Non Convertible WRAPAROUND
Empower® 2	Dr. Korn Tube	Convertible Single
Mini Master Series™	Inconel	Convertible Double
Master Series™	Funneled Entrance	Convertible Triple
iFit®	Non Convertible	Nola Buccal Tube
LP® Low Profile	Non Convertible Double	
Slim Tube™	Non Convertible Triple	
Cross Tubes	Non Convertible Lip Bumper	

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 62336-1, EN ISO 14971, EN 1041, EN ISO 10993-1, 10993-3, 10993-5, 10993-11, EN 980

Other Standards: ISO 10993-10, ISO 7405, ISO 10271, ISO 27020, ISO 15223-1, ISO 15223-2, ISO 9333

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 according to the Directive 93/42/EEC on Medical Devices.

Signed for and on behalf of:

American Orthodontics
Sheboygan, WI

Company Representative: Trang Adams / Regulatory Affairs Specialist

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