

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201603 -04d

Certificate Issue Date: 03/07/16

Certificate Expiry Date: 11/22/17

This certificate is valid until Expiry Date listed above.

Medical Device Detail:

Product/Family Category:

Buccal Tubes

Classification: *Classification is according to Directive 93/42/EEC, Annex IX*

Class IIa per Rule 5, 3rd indent

Product(s) Tradename(s):

Empower® 2

Empower® 2 Self-Ligating

System(s)/Configuration(s) associated with Product(s) Tradename(s):

Empower® 2 (Weldable:Convertible Double: Maxillary 1st Molar)

Empower® 2 (Weldable:Convertible Double: Mandibular 1st Molar)

Empower® 2 (Weldable:Convertible Single: Maxillary 1st Molar)

Empower® 2 (Weldable:Convertible Single: Mandibular 1st Molar)

Empower® 2 Self-Ligating (Direct Bond: Convertible: Maxillary 1st Molar)

Empower® 2 Self-Ligating (Direct Bond: Convertible: Mandibular 1st Molar)

Empower® 2 Self-Ligating Double (Direct Bond: Convertible: Mandibular 1st Molar)

Empower® 2 Self-Ligating Double (Direct Bond: Convertible: Maxillary 1st Molar)

CE Authorized Representative:

Emergo Europe
Molenstraat 15
2513 BH The Hague, The Netherlands

Assessment Details:

Notified Body: TUV Austria

CE Certificate #: TUV-A-MT-1/13/QE011

Issue Date: 05/01/13

Route of Directive: Annex VI *of the Directive 93/42/EEC on Medical Devices.*

Standards Applied:

Harmonized Standards: IEC ISO 62336, EN ISO 14971, EN 1041, EN ISO 10993-1, 10993-3, 10993-5, 10993-10, 10993-11

Other Standards: ISO 10271, ISO 27020, ISO 7405, ISO 9333, ISO/TS 11405

Declaration statement:

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classifications rules before being shipped. The above products are in compliance with Annex I Essential Requirements of Directive 93/42/EEC. The product is CE marked.

Signed for and on behalf of:

American Orthodontics
Sheboygan, WI

Company Representative:


Trang Adams / Regulatory Affairs Specialist

