

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201706 -11H

Certificate Issue Date: 06/13/17
Certificate Expiry Date: 09/17/18
This certificate is valid until Expiry Date listed above.

Medical Device Detail:

Product/Family Category:
Orthodontic Wires

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

Product(s) Tradename(s):

Therma-Ti®
Therma-Ti® Lite
Therma-Ti® "D"
Tritanium™
Beta Titanium Wire
Stainless Steel Wire
Force Two NiTi Wire
Gold Tone
Stainless Steel Multi-Strand

CE Authorized Representative:

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Assessment Details:

Notified Body: UL International (UK) Ltd.
CE Certificate #: 858.170201
Issue Date: 02/01/17
Route of Directive: Annex II (excluding Sect. 4)
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, EN ISO 11140-1

Other Standards: ISO 10993-10, ISO 7405, ISO 10271, ISO 15223-1, ISO 15223-2, ISO 15841

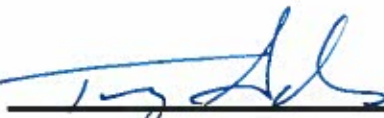
Declaration statement:

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:



Travis Adams / Regulatory Affairs Specialist

