

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201603 -16a

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:

Instruments

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

Class I per Rule 5, 1st indent

Product(s) Tradename(s):

Omega®
MasterLine Instruments™
Bracket & Band Placing Instrument
Ligating Instruments

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

Omega® (Pliers)
Omega® (Cutter, Bracket Remover, Band Remover)
MasterLine Instruments™ (Band Slitting Instrument)
Bracket & Band Placing Instrument (Direct Bond Bracket Holders, Positioner, Band Seater)
Bracket & Band Placing Instrument (High Heat Bite Stick, Band Pusher, Tweezers)
Ligating Instruments (Ligature Director, Single End Explorer, Force Module Separator, Ligature Tying Pliers)
Ligating Instruments (Mathieu Needle Holder, Smaha Forceps, Hemostat)

CE Authorized Representative:

Emergo Europe
Molenstraat 15
2513 BH The Hague, The Netherlands

Assessment Details:

Route of Directive: VII 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: N/A

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

