

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201603 -09c

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:

Fixed & Functional

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

Class IIa per Rule 5, 3rd indent

Product(s) Tradename(s):

Quick Fix
Alexander Lip Bumper
Lip Bumper
Bondable Space Maintainer
Bondable Retainer

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

Alexander Lip Bumper (with Hook, without Hook)
Lip Bumper (with Cuspid Hook, without Cuspid Hook, Korn)
Bondable Retainer (Upper Central to Central, Upper Lateral to Lateral, Lower Cuspid to Cuspid)
Bondable Retainer (Upper Central to Central Kit, Upper Lateral to Lateral Kit, Lower Cuspid to Cuspid Kit)

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 7405, ISO 9333, ISO 20795-1

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

