

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201805 -13

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: Orthodontic Supplies/Accessories

Classification: Class I per Rule 5, 1st & 2nd 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):

Orthodontic Wax	Impressa/Chrome™	Impressa/Sure™
Orthodontic Silicone Wax	Applicator Tips	YC3 Shield / Muh Shield
Ortho Wax Bites	Elastic Placers	Cotton Roll Holders
Photographic Mirror	Toothbrushes	
Impression Tray	Ultra-Guard Mouthguard	
American Cheek Retractors	Protraction Facemask	
Clear Cheek Retractors	NOLA Dry Field System	
Expando Cheek Retractors	Debond Wafers	
Laminated Bite Wafers	UniMarc Arch Wire Markers	

CE Authorized Representative:

MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert
Germany

Assessment Details:

Route of Directive: VII of the Directive 93/42/EEC on Medical Devices

Standards Applied:

Harmonized Standards: EN ISO 13485, IEC 62336, EN ISO 14971, EN 1041, EN 980

Other Standards: ISO 15223-1, ISO 15223-2

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

