

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201805 -15b

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 Instruments

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):

Specialty Instruments (Distal Twister)	Specialty Instruments (Band Seater/Cement Scaler)
Specialty Instruments (Convertible Cap Remover, Spatula)	Harmony Instruments (Scaler/Band Pusher)
Specialty Instruments (Dontrix Gauge, Boone Gauge)	Harmony Instruments (Open/Closer)
Specialty Instruments (Force Gage)	Harmony Instruments (Hu-Friedly Explorer/Ligature Director)
Specialty Instruments (Alexander Bracket Placement Guide)	
Specialty Instruments (Adhesive Remover)	
Specialty Instruments (Wire Cutter)	
Specialty Instruments (Bracket Placement Guide)	
Specialty Instruments (Mouth Mirror)	
Specialty Instruments (Band Contouring, Nance Closing Loop,)	

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:


Travis Adams / Regulatory Affairs Specialist

