

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201805 -04

Medical Device Detail:

Product/Family Category: Brackets and Bondable Devices

Classification: Class IIa *per Rule # 5, 3rd indent*

Classification is according Directive 93/42/EEC; Annex IX

Product(s) Tradename(s):

See Attachment A

UMDNS Code:

See Attachment A

CE Authorized Representative:

MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert
Germany

Assessment Details:

Notified Body: PCBC Warsaw, Poland

CE Certificate #: 1434-MDD-457/2019

Notified Body #: 1434

Issue Date: 08/29/19

Route of Directive: Annex II

of the Directive 93/42/EEC on Medical Devices.

Standards Applied:

Harmonized Standards: EN 1641, ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 7405, ISO 20795-2, ISO 27020, ISO 9333

Other Standards: ISO 13485, ISO 14971, EN 1041, ISO 15223-1, ISO 15223-2, IEC/ISO 62366-1

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 under Directive 93/42/EEC on Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Signed for and on behalf of:

American Orthodontics
Sheboygan, WI

Company Representative:



Andre Leak / Regulatory Affairs Coordinator

Date:

9/6/19





ATTACHMENT A

Product/Family Category: Brackets

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

<u>Product(s) Tradename(s):</u>	UMDNS Code:	GMDN Code
Custom Rx (SS brackets)	16360	46581
Empower® 2	16360	46581
Forever Gold™ 24K	16360	46581
Iconix™	16360	46581
LP® Low Profile	16360	46581
Master Series™	16360	46581
Mini Master Series™	16360	46581
Mini Standard Edgewise	16360	46581
Mini Tweed	16360	46581
Silkon Plus™	16360	46582
Empower Clear®	16360	58818
Radiance Plus®	16360	58937
Orthodontic Space Maintainer	none	31754
Bondable Retainer	none	35310
Stainless Steel Flat Braided Lingual Retainer	none	35310
Coil Eyelet	none	none
Eyelets	none	none
Buttons (Stainless Steel)	none	none
Bite Blocks	none	none
Ball Hooks	none	none
Tongue Director	none	none