



Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics Corp
3524 Washington Avenue
Sheboygan, WI 53081, USA

Certificate Number: 201805 -03

Rev 3



Medical Device Detail:

Product/Family Category: Bondable Devices

Classification: Class IIa *per Rule # 5*

Classification is according to 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-400/2021

Notified Body #: 1434

Issue Date: 05/25/21

Route of Directive: Annex II

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

Standards Applied:

Harmonized Standards: EN 1641:2009, EN ISO 10993-1:2009, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016

ISO 10993-1:2018, ISO 14971:2019, ISO 7405:2018, ISO 27020:2019, IEC 62366-1:2015,

Other Standards: ISO 20417:2021

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 Corp
Sheboygan, WI, USA

Date of Conformity Assessment:

May 25th, 2021

Company Representative:

Frederick Guesneau / Manager Quality and Regulatory Affairs



ATTACHMENT A

Product/Family Category: Brackets and Bondable Devices

Classification: Class IIa *per Rule # 5*

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

<u>Product(s) Tradename(s):</u>	GMDN Code	UMDNS Code:
<i>Custom Rx (SS brackets)</i>	46581	16360
<i>Empower® 2</i>	46581	16360
<i>Forever Gold™ 24K</i>	46581	16360
<i>Iconix™</i>	46581	16360
<i>LP® Low Profile</i>	46581	16360
<i>Master Series™</i>	46581	16360
<i>Mini Master Series™</i>	46581	16360
<i>Mini Standard Edgewise</i>	46581	16360
<i>Mini Tweed</i>	46581	16360
<i>SL Brackets</i>	46581	16360
<i>Silkon Plus™</i>	46582	16360
<i>Empower® Clear</i>	58818	16360
<i>Radiance Plus®</i>	58937	16360
<i>Ceramic Button</i>	58937	n/a
<i>Orthodontic Space Maintainer</i>	35310	18082
<i>Bondable Retainer (and Stainless Steel Flat Braided Lingual Retainer)</i>	35310	13370
<i>Ball Hooks</i>	63223	12028
<i>Bite Blocks</i>	62683	10405
<i>Buttons (Stainless Steel)</i>	46581	12028
<i>Coil Eyelet</i>	63223	12028
<i>Eyelets</i>	63223	12028
<i>Tongue Director</i>	62683	12028
<i>Utility Traction Hook (U/T Hook)</i>	63223	n/a