

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics Corporation
3524 Washington Avenue
Sheboygan, WI 53081, USA
SRN: US-MF-000007702
SRN Importer: NL-IM-000012767

Certificate Number: MDR 752691 R000

Medical Device Detail:

Device Schedule: Class IIa, Custom-made and other devices
Product/Family Category: Orthodontic Brackets, Bondable Devices & Tubes
Classification: Class IIa
Classification is according to Regulation 2017/745; Annex VIII, Rule 5



Product(s)
See Attachment A

GMDN Code:
See Attachment A

Basic UDI-DI:
See Attachment A

CE Authorized Representative:

MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7
66386 St. Ingbert
Germany

Assessment Details:

Notified Body: BSI Group the Netherlands B.V
CE Certificate #: MDR 752691
Notified Body #: 2797
Issue Date: 2023-01-19
Route of Directive: Annex IX, Chapters I and III
Of the Regulation 2017/745 on Medical Devices

Standards Applied:

Harmonized Standards: EN ISO 13485:2016, EN ISO 15223-1:2021

Other Standards: ISO 10993-1:2018, ISO 7405:2018, ISO 27020:2019, IEC 62366-1:2015, ISO 14971:2019, ISO 20417:2021, BS EN 1041:2008, ISO/TR 20416:2020

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 comply with Annex I General Safety and Performance Requirements under Regulation 2017/745 on Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

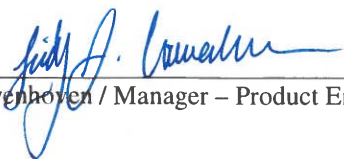
Signed for and on behalf of:

American Orthodontics
Sheboygan, WI 53081, USA

Place of Issue:

American Orthodontics
Sheboygan, WI 53081, USA

Company Representative:


Lindy Couwenhoven / Manager – Product Engineering and Regulatory Affairs

Date: 23 - January - 2023



American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

www.americanortho.com

1 800 558 7687
+1 920 457 5051 office
+1 920 457 1485 fax

ATTACHMENT A

Intended Purpose: American Orthodontics' devices operate together with other orthodontic devices to apply forces to teeth. Under the supervision of a trained dental professional or orthodontist, this may result in changes to the position of teeth. American Orthodontics' devices are intended and labeled for single-use or single patient use only. American Orthodontics does not condone or support the reuse or reprocessing of single-use devices.

GMDN Code – 46581:	Orthodontic Brackets, Metal	Basic UDI-DI: 0190746000003PN
- Empower Brackets - Mini Master Series Brackets - Master Series Brackets - Mini Tweed	- LP Low Profile - Forever Gold 24K - Mini Standard Edgewise	- Buttons - Iconix Brackets - Stainless Steel Bracket
GMDN Code – 58937:	Orthodontic Brackets, Ceramic	Basic UDI-DI: 0190746000004PQ Basic UDI-DI: 0190746000001PJ (VM)
- Radiance Plus - 20/40 (VM)	- Ceramic Button	- Ceramic Button (VM)
GMDN Code – 58818:	Self-Ligating Orthodontic Brackets	Basic UDI-DI: 0190746000005PS
- Empower Clear		
GMDN Code – 35310:	Bondable Retainer	Basic UDI-DI: 0190746000009Q2
- Bondable Retainer		
GMDN Code – 62683:	Tongue Director	Basic UDI-DI: 0190746000007PW
- Tongue Director	- Bite Blocks	
GMDN Code – 31759:	Orthodontic Tube	Basic UDI-DI: 0190746000012PP
- Empower Tubes - Mini Master Series Tubes - Master Series Tubes	- iFit - LP - Slim Tube	- Buccal Tubes - Iconix Tubes
GMDN Code – 63223:	Orthodontic Power Arm	Basic UDI-DI: 0190746000008PY Basic UDI-DI: 0190746000002PL (VM)
- UT Hook	- Eyelets	- Hooks