

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-459/2019

Notified Body #: 1434

Issue Date: 08/29/2019

Route of Directive: Annex V

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:

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:

9/9/19





FORM: FM-RA-100.1
REV: 08 (02/12/2018)

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>	<u>UMDNS Code:</u>	<u>GMDN Code</u>
20/40 Ceramic Brackets™	16360	58937
Eruption Appliance	none	none
Ceramic Buttons	none	none