

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

Certificate Number: 201805 -07

Medical Device Detail:

Product/Family Category: Orthodontic Supplies (OBL)

Classification: Class I per Rule 5

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

Product(s) Tradename(s):

See Attachment A

GMDN Code:

See Attachment A



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

Notified Body: PCBC Warsaw, Poland

Notified Body #: 1434

Standards Applied:

Harmonized Standards: EN ISO 10993-1:2009, EN ISO 10993-3:2014, EN ISO 10993-5:2009, BS EN ISO 10993-11:2018, ISO 13485:2016, EN ISO 14971:2012, EN 1041:2008, EN ISO 15223-1:2016

Other Standards: ISO 10993-1:2018, BS EN ISO 10993-10:2013, ISO 7405:2018, ISO 20795-2:2013, IEC 62366-1:2015

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:


Frederick Guesneau / Manager Regulatory Affairs and Quality

Date: 10-13-20



FORM: FM-RA-100.1

REV: 08 (02/12/18)

ATTACHMENT A

Product/Family Category: Orthodontic Supplies (OBL)

Classification: Class I *per Rule 5*

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

Product(s) Tradename(s):

Cheek Retractors (American)

Cheek Retractors (Clear)

Impressa/Chrome™ Alginate

Laminated Bite Wafers

Ortho Wax Bites

Orthodontic Wax

Wax Archwire Markers

GMDN Code:

44828

13380

35863

38584

45251

45251

45251