

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081, USA

Certificate Number: 201805-18

Rev 4

Medical Device Detail:

Product/Family Category: Orthodontic Instruments

Classification: Class I

Classification is according Medical Device Directive (MDD) 93/42/EEC; Annex IX, Rule 5

Class Ir

Classification is according Medical Device Regulation (MDR) (EU) 2017/745; Annex VIII, Rule 5



Product(s) Tradename(s):

See Attachment A

GMDN Code:

See Attachment A

Basic UDI-DI:

See Attachment A

CE Authorized Representative:

MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert
Germany

Assessment Details:

Route of Directive: Medical Device Directive (MDD) 93/42/EEC

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

Other Standards:

ISO 10993-1:2018, ISO 14971:2019, ISO 7405:2018, ISO 27020:2019, IEC 62366-1:2015, 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 General Safety and performance Requirements under Medical Device Regulation (MDR) (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer.

Signed for and on behalf of:

American Orthodontics
Sheboygan, WI, USA

Date of Conformity Assessment:

May 25th, 2021

Company Representative:


Frederick Guesneau / Manager Quality and Regulatory Affairs

**AO AMERICAN
ORTHODONTICS**
ATTACHMENT A

Product/Family Category: Orthodontic Instruments

Classification: Class I

Classification is according Medical Device Directive (MDD) 93/42/EEC; Annex IX, Rule 5

Product(s) Tradename(s):

Dental Explorer (*Single ended explorer*)

Orthodontic Scalar (*band seater double sided, band pusher*)

Orthodontic Pliers (*Hollow Chop, Nance*)

DB Adhesive Remover Double Ended

GMDN Code:

Basic UDI-DI:

35812

0190746000068QJ

31801

0190746000069QL

33209

0190746000070Q5

38530

0190746000071Q7