

## Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

**Company Information:**

American Orthodontics  
3524 Washington Avenue  
Sheboygan, WI 53081

**Certificate Number:** 201805 -03

**Certificate Issue Date:** 05/22/18

**Certificate Expiry Date:** 11/20/22

*This certificate is valid until Expiry Date listed above.*

**Medical Device Detail:**

**Product/Family Category:** Composite Bracket

**Classification:** Class IIa *per Rule 5, 3rd indent*

*Classification is according to Directive 93/42/EEC, Annex IX*

**Intended Use:** American Orthodontics' products are used for the orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist.

**Product(s) Tradename(s):**

Silkon Plus

**CE Authorized Representative:**

MT Promedt Consulting GmbH  
Altenhofstrasse 80  
66386 St. Ingbert  
Germany

**Assessment Details:**

**Notified Body:** UL International (UK) Ltd.

**CE Certificate #:** 840.180522

**Notified Body #:** 0843

**Issue Date:** 05/22/18

**Route of Directive:** Annex II

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

**Standards Applied:**

**Harmonized Standards:** EN ISO 13485, IEC 62336-1, EN ISO 14971, EN 1041, EN ISO 10993-1, 10993-3, 10993-5, 10993-11, EN 980

**Other Standards:** ISO 10993-10, ISO 7405, ISO 11405, ISO 27020, ISO 15223-1, ISO 15223-2, ISO 20795-1

**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 according to the Directive 93/42/EEC on Medical Devices.*

**Signed for and on behalf of:**

American Orthodontics  
Sheboygan, WI

**Company Representative:**



Trang Adams / Regulatory Affairs Specialist

