

## Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

### Company Information:

American Orthodontics  
3524 Washington Avenue  
Sheboygan, WI 53081

Certificate Number: 201603 -16c

Certificate Issue Date: 03/07/16

Certificate Expiry Date: 11/22/17

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

### Medical Device Detail:

Product/Family Category:

Instruments

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

*Class I per Rule 5, 1st indent*

Product(s) Tradename(s):

Empower Instrument  
Vision LP Instruments  
T3 Instruments  
Harmony Instruments

System(s)/Configuration(s) associated with Product(s) Tradename(s):

Vision LP Instruments (Single-Ended, Double-Ended)  
T3 Instruments (Open/Close Instrument, Hu-Friedy, Hu-Friedy T3 Positioning Instrument)  
Harmony Instruments (Open/Close, Scaler/Band Pusher)  
Harmony Instruments (Hu-Friedy Explorer/Ligature Director,)

### CE Authorized Representative:

Emergo Europe  
Molenstraat 15  
2513 BH The Hague, The Netherlands

### Assessment Details:

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

### Standards Applied:

Harmonized Standards: IEC ISO 62336, EN ISO 14971, EN 1041, EN ISO 10993-1, 10993-3, 10993-5, 10993-10, 10993-11

Other Standards: N/A


### Declaration statement:

*Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classifications rules before being shipped. The above products are in compliance with Annex I Essential Requirements of Directive 93/42/EEC. The product is CE marked.*

### Signed for and on behalf of:

American Orthodontics  
Sheboygan, WI

Company Representative:

  
Trang Adams / Regulatory Affairs Specialist

