

APPROVAL
EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60022365 0001

Report No.: 30793582 001

Manufacturer: Ultimate Wireforms, Inc.
Ultimate NiTi Technologies
200 Central St.
Bristol, CT 06010
USA

Scope: Design/Development and Production of Orthodontic Products
Products: see attachment
Replaces Approval, Registration No.: HD 60005604 0001

Date of Expiry: 18.09.2013

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Cologne, 23.09.2008


B. Ludovico

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: HD 60022365 0001
Report No.: 30793582 001

Manufacturer: Ultimate Wireforms, Inc.
Ultimate NiTi Technologies
200 Central St.
Bristol, CT 06010
USA

Scope: Products:

- Stainless Steel Orthodontic Wire
- Nickel Titanium Orthodontic Wire
- Beta III-CNA[®] Orthodontic Wire
- Nickel Titanium Orthodontic Springs
- Stainless Steel Orthodontic Springs
- Stainless Steel Orthodontic Accessories
- Utilloy Orthodontic Wire
- Orthodontic Brackets and Buccal Tubes

Certification Body

Cologne, 23.09.2008


B. Ludovico