

## APPROVAL

EC Directive 93/42/EEC Annex V, Article 3  
Quality Assurance System Production

Registration No.: DD 60024795 0001

Report No.: 30892682 001

**Manufacturer:** Acme Monaco Corporation  
75 Winchell Drive  
New Britain CT 06052  
USA

**Scope:** Production of Orthodontic Wire Devices

Products: see attachment  
Production facilities: see attachment

Replaces Approval, Registration No.: DD 60020460 0001

**Date of Expiry:** 12.04.2014

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 17.04.2009



Notified Body

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.:** DD 60024795 0001  
**Report No.:** 30892682 001

**Manufacturer:** Acme Monaco Corporation  
75 Winchell Drive  
New Britain CT 06052  
USA

**Scope:**

Products:

Orthodontic Wire Devices:

- Archwires
- Ligature
- Retainer Wire
- Auxiliaries and Coil Springs

Production Facilities:

- Acme Monaco Corporation  
75 Winchell Drive, New Britain, CT 06052 USA
- Acme Monaco Corporation  
205 Cross Street, Presque Isle, ME 04769 USA
- Acme Monaco Corporation  
500 Central Drive, Presque Isle, ME 04769 USA

Cologne, 17.04.2009



**Certification Body**

*[Signature]*  
B. Ludovico