



APPROVAL

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

Registration No.: DD 60007524 0001

Report No.: 30393028 001

Manufacturer: Acme-Monaco Corporation
75 Winchell Dr.
New Britain, CT 06052
USA

Scope: Production of Orthodontic Wire Components and Medical Assemblies

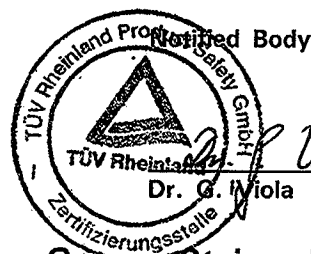
Products: see attachment
Manufacturing facility: see attachment

Replaces Approval, Registration No.: DD 9811495 01

Date of Expiry: 14.03.2009

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, 15.03.2004



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



Doc. 1/1, Rev. 1

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

Attachment to
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Manufacturer: Acme-Monaco Corporation
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USA

Scope:

Products:

Orthodontic Wire Components:

- Archwires
- Ligature Ties
- Retainer Wire
- Auxilliaries and Coil Springs

Production facilities:

- Acme Monaco Corporation
204 Cross Street, Preque Isle, ME 04769 USA
- Acme Monaco Corporation
75 Winchell Drive, New Britain, CT 06052, USA

Cologne, 18.08.2005



P. Viola
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