

Certificate

The Certification Body of
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization

Acme Monaco Corporation
75 Winchell Drive
New Britain CT 06052
USA

has established and applies a quality management system for medical devices
for the following scope:

**Production of Orthodontic Wire Devices,
Guidewires and Medical Assemblies**
Facilities: see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2003

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60024796 0001

An audit was performed. Report No.: 30892682 001

This Certificate is valid until: 12.04.2014

Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Cologne, 17.04.2009




R. Ludovico

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

**Attachment to
Registration No.:** SX 60024796 0001
Report No.: 30892682 001

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

Scope: Facilities:

- Acme Monaco Corporation
75 Winchell Drive, New Britain, CT 06052 USA
Scope: Activities related to manufacturing.
- Acme Monaco Corporation
205 Cross Street, Presque Isle, ME 04769 USA
Scope: Activities related to manufacturing.
- Acme Monaco Corporation
500 Central Drive, Presque Isle, ME 04769 USA
Scope: Activities related to manufacturing.



Cologne, 17.04.2009



[Signature]
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