ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 093739 0015 Rev. 01

Holder of Certificate: **Acme Monaco Corporation**
75 Winchell Road
New Britain CT 06052
USA

Certification Mark:

Scope of Certificate: **Design and Development and Production of Non-Sterile Medical Orthodontic Wire Devices, Medical Guidewires, and Medical Stylets. The Provision of Manufacturing Services for Non-Sterile Medical Guidewires, Orthodontic Wires Devices, Springs, Stampings, Stylets, and Wire Forms.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 093739 0015 Rev. 01

Report No.: 72174878

Valid from: 2022-09-02
Valid until: 2025-03-04

Date, 2022-09-02

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Acme Monaco Corporation
1450 Central Drive, Presque Isle ME 04769, USA

Production of Non-Sterile Medical Orthodontic Wire Devices, Medical Guidewires, and Medical Stylets. The Provision of Manufacturing Services for Non-Sterile Medical Guidewires, Orthodontic Wires Devices, Springs, Stampings, Stylets, and Wire Forms.

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