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Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 093739 0011 Rev. 00

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

EC-Representative: Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover, GERMANY

Product Category(ies): Non-Sterile Orthodontic Wire Devices

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72143585

Valid from: 2019-05-06
Valid until: 2024-03-04

Date, 2019-05-06

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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No. G1 093739 0011 Rev. 00

Facility(ies):

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

Acme Monaco Corporation
75 Winchell Road, New Britain CT 06052, USA

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