



Product Service

# EC-CERTIFICATE

## Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2S 08 03 65264 001

**Manufacturer:** Accellent Inc. S.A. De C.V.  
 1525 Hertz Street  
 Industrial Park J. Bermudez  
 Ciudad, Juarez  
 32470 Chihuahua  
 MEXICO

**EC-Representative:** Accellent Cardiology Inc  
 5 Westlink Park  
 Oranmore  
 Galway  
 IRELAND

**Product Category(ies):** Disposable Guidewires

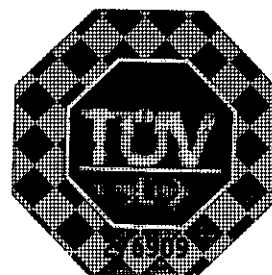
The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective product / product categories and conforms to the provisions of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:** DM708831

**Valid until:** 2012-05-19

**Date,** 2008-05-21

Reiner Krumme



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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**Facility(ies):**                    **Accellent Inc. S.A. De C.V.**  
**1525 Hertz Street, Industrial Park J.**  
**Bermudez, Ciudad, Juarez, 32470**  
**Chihuahua, MEXICO**

