



466 W. Arrow Hwy. • Unit H • San Dimas, California 91773  
909.394.4916 • fax: 909.305.0895  
www.advancedinfusion.com

## DECLARATION OF CONFORMITY

**MANUFACTURER:** Advanced Infusion, Inc.  
290 S. Alma School Road, Suite 1  
Chandler, Arizona USA 85224

**EUROPEAN REPRESENTATIVE:** Donawa Lifescience Consulting Srl  
Piazza Albania, 10  
00153 Rome, Italy

**PRODUCT:** Introducers: Needles and Tunnelers  
**REF #:** NDL16-4, NDL16-6, NDL16-8, NDL16-10, and TUN13-10

**CLASSIFICATION:** Class IIa, Rule 6 according to Annex IX of the MDD

**CONFORMITY ASSESSMENT ROUTE:** Annex II of Directive 93/42/EEC

ADVANCED INFUSION DECLARES THAT THE ABOVE MENTIONED PRODUCTS CONFORM TO THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES, AS AMENDED BY DIRECTIVE 2007/47/EC. ALL TECHNICAL DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

TO THE BEST OF ITS KNOWLEDGE, INFORMATION AND BELIEF, ADVANCED INFUSION, INC., IS IN COMPLIANCE, IN ALL MATERIAL RESPECTS WITH ITS QUALITY MANAGEMENT SYSTEM ACCORDING TO ISO 13485 AND ITS GOOD FAITH UNDERSTANDING OF THE REQUIREMENTS OF THE COUNCIL DIRECTIVE 93/42/EEC. THIS DECLARATION IS ISSUED UNDER THE SOLE RESPONSIBILITY OF ADVANCED INFUSION, INC.

**NOTIFIED BODY:** DQS 0297 – GmbH

**(EC) CERTIFICATE(S):** EC Certificate Number: 291659 MR2  
Issued: 2008-06-28  
Valid Until: 2011-06-27

**QUALITY MANAGEMENT SYSTEM:** DIN EN ISO 13485 (2003)

**CERTIFICATE(S):** Certificate Number: 291659 MP23  
Issued: 2008-06-28  
Valid Until: 2011-06-27

**SIGNATURE:**

  
James Christensen  
Regulatory Affairs

DEC 30, 2009  
Date