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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