



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 Roma

PRODUCT: Alpha Cath™ Infusion Catheter
Multi Drip® Infusion Catheter
[see attached list]

CLASSIFICATION: Class IIa, Rule 7 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

(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: 2010-06-27

SIGNATURE:


James Christensen
Regulatory Affairs

MAR 26, 2010
Date



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Alpha Cath™ Infusion Catheters

PAC05	Alpha Cath™ Infusion Catheter, 0.5 mL/hr Flow Rate
PAC10	Alpha Cath™ Infusion Catheter, 1.0 mL/hr Flow Rate
PAC20	Alpha Cath™ Infusion Catheter, 2.0 mL/hr Flow Rate
PAC40	Alpha Cath™ Infusion Catheter, 4.0 mL/hr Flow Rate
PAC60	Alpha Cath™ Infusion Catheter, 6.0 mL/hr Flow Rate

Alpha Cath™ Infusion Catheters with Luer

PAC30L	Alpha Cath™ Infusion Catheter with Luer, 3.0 mL/hr Flow Rate
PAC50L	Alpha Cath™ Infusion Catheter with Luer, 5.0 mL/hr Flow Rate
PAC80L	Alpha Cath™ Infusion Catheter with Luer, 8.0 mL/hr Flow Rate
PAC100L	Alpha Cath™ Infusion Catheter with Luer, 10.0 mL/hr Flow Rate

Multi Drip® Infusion Catheters

PMD20-6	Multi Drip® Infusion Catheter, 2.0 mL/hr Flow Rate, 6 cm Infusion Zone
PMD20-12	Multi Drip® Infusion Catheter, 2.0 mL/hr Flow Rate, 12 cm Infusion Zone
PMD20-24	Multi Drip® Infusion Catheter, 2.0 mL/hr Flow Rate, 24 cm Infusion Zone
PMD40-6	Multi Drip® Infusion Catheter, 4.0 mL/hr Flow Rate, 6 cm Infusion Zone
PMD40-12	Multi Drip® Infusion Catheter, 4.0 mL/hr Flow Rate, 12 cm Infusion Zone
PMD40-24	Multi Drip® Infusion Catheter, 4.0 mL/hr Flow Rate, 24 cm Infusion Zone

End of List