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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 Consulting Srl  
Piazza Albania, 10  
00153 Roma

**PRODUCT:** Alpha Infusion Pump

**CLASSIFICATION:** Class IIa, Rule 11 according to Annex IX of the MDD

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

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE TRANSITION INTO NATIONAL LAW OF THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

**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: 2011-06-27

**SIGNATURE:**   
James Christensen  
Regulatory Affairs