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DECLARATION OF CONFORMITY

MANUFACTURER: Advanced Infusion, Inc.
920 E. University Drive, Suite D202
Tempe, Arizona USA 85281

EUROPEAN REPRESENTATIVE: Donawa Consulting Srl
Piazza Albania, 10
00153 Roma

PRODUCT: STA Cath[®] Attachable Infusion Catheter

CLASSIFICATION: Class IIa, Rule 5 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