EC Certificate - Full Quality Assurance System

Supplementary Information to CE 699333

Issued To:

Arrow International LLC
Subsidiary of Teleflex Incorporated
3015 Carrington Mill Blvd.
Morrisville
North Carolina
27560
USA

Number	Device Name	Intended purpose per IFU
Class III		
MD 0100	Berman Angiographic Balloon Catheters and Kits and Reverse Berman Angiographic Balloon Catheter and Kits	See CE 699365
MD 0100	Balloon Wedge Pressure Catheters and Kits	See CE 699366
MD 0100	Intra-Aortic Balloon Catheter Kits	See CE 699367
MD 0102	Arrow® PICC with Arrowg+ard Blue Advance™ Technology	See CE 699337
Class IIb		
MD 1101	AutoCAT3 Intra Aortic Balloon Pump	The AC3 Intra-Aortic Balloon Pump is clinically indicated for use for the following conditions: Acute Coronary Syndrome Cardiac and Non-Cardiac Surgery Complications of Heart Failure
MD 1101	Intra-Aortic Balloon Pump AutoCat 2	There are three primary indications for IABP use; Acute Coronary Syndrome Cardiac and Non-Cardiac Surgery Complications of Heart Failure

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