

# Certificate

## Design Examination

No. CE 02169



Issued to:

**Millar Instruments Inc.**  
**6001-A Gulf Freeway**  
**Houston**  
**Texas**  
**77023-5417**  
**USA**

In respect of:

**MILLAR Mikro Tip catheter pressure and velocity transducer**

On the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 4.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

A handwritten signature in black ink, appearing to read 'David Ford', with a horizontal line underneath it.

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David Ford, Director, Healthcare and Testing Services

First Issued: 17 Nov 1998

Date: 4 Dec 2009

Expiration Date: 16 Feb 2014

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*Conditions of Approval*

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.

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# Certificate

## Supplementary Information to CE 02169

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**Houston**  
**USA**

Range of product parameters:					
Family	Cardiology (Catheters)				
Indications for Use	Angiographic-Pressure	Pressure only	Pressure Volume (electrodes)	Velocity	Specials
Model Pre-fix	SPC-XXXX	SPC-XXXX	SPC-XXXX	SVPC-XXXX	SSD-XXXX
Materials: Polyurethane-Woven Dacron (PUWD) Polyurethane (PU) Polyamide (Nylon) Tecoflex	Polyurethane (PU) Polyamide (Nylon)	ALL	Polyurethane (PU) Polyamide (Nylon)	ALL	ALL
Diameter (F)	5 - 6 F	2 - 8.5 F	5 - 7 F	6 - 8 F	2 - 8 F
Length (cm)	105	65 - 140	125	65 - 140	65 - 140
2F /3F Sensor	3F	2 / 3 F	3F	3F	2 / 3 F
Guidewire Lumen (0.xx"/No)	.028	.032-.038"/No	NO	NO	Yes / No
SS. Case-tube / Wall Mount	Wall Mount	SS. Case-tube / Wall Mount	Wall Mount	SS. Case-tube / Wall Mount	SS. Case-tube / Wall Mount
Catheter splice	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
Pigtail / Ball	Pigtail	Pigtail / Ball	Pigtail	Ball	Pigtail / Ball
Tip Characteristics	Straight / Curve	Straight / Curve	Straight	Straight / Curve	Straight / Curve
Curve Characteristics - Degrees / Length	155 / Short - Long	45-90 / Short - Long	N/A	45-90 / Short - Long	45 -90 / Short - Long
Sensor Coating	RTV-112/A-271	RTV-112/A-271	RTV-112/A-271	RTV-112/A-271	RTV - 112/A-271
Number of sensors (velocity sensors)	1	1-5	1-2	1-2 (1-2)	1 - 5
Sensor Location / Spacing from Tip (cm or electrode (E) location)	Wall mount at Tip	Wall-Case Mount at Tip; 3-5 cm proximal	4 <sup>th</sup> -6 <sup>th</sup> E & 5cm Prox. 12 <sup>th</sup> E	Wall-Case Mount at Tip; 3-5 cm proximal	Wall -Case Mount at Tip; 1.5-10 cm proximal
Number of Electrodes	N/A	N/A	8 - 12	N/A	4 - 12
Electrode Spacing (mm)	N/A	N/A	7 - 12	N/A	2 - 12
Injection Rate (ml/m or ml/s)	12-16 ml/s	5 ml/m - 15 ml/s	N/A	N/A	5 ml/m - 15 ml/s
Connector	Low Profile	Viking / Low Profile	Low Profile	Viking	Viking / Low Profile
Re-Usable	NO	25 - 50X	5X	25 - 50X	5 - 50X

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### History of Certificate

Date	Reference Number	Action
17 November 1998	MD000441	First issue
27 April 2001	MD000441	Change of Supplementary Information
25 February 2004	10055414	Change of Supplementary Information New certificate format Five years certificate renewal
14 November 2008	10100471	Certificate renewal
12 February 2009	10103073	Certificate renewal
04 December 2009	10110606	Change of OEM Catheter Supplier for the Angiographic and Pressure Volume Catheters

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