

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No.**CE 01110****Issued To:**

Cordis Corporation
14201 North West 60th Avenue
Miami Lakes
Florida
33014
USA

In respect of:**Cordis Guiding Catheters**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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



Frank Lee, EMEA Compliance & Risk Director

First Issued: 03 January 1996**Date: 13 December 2015****Expiry Date: 02 January 2021**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 01110

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<u>Guiding Catheter Cat. Nos</u>	<u>Family Name</u>	<u>French Size</u>
511-XXX, 511-XXXX, SMXXXX, SMXXXXX series	Vista brite tip	10
588-8XX, 588-8XXX, 8XXE, 8XXP, 8XXT, SMXXXX, SMXXXXX series	Long Brite tip	8F
598-9XX, 9XXE, 9XXP, 9XXT, SMXXXX, SMXXXXX series	Vista brite tip	9
778-XXX-XX, XXX, XE, SMXXXX, SMXXXXX series	Vista Brite tip	7F
<u>Guiding Catheter Cat. Nos</u>	<u>Family Name</u>	<u>Type/Family</u>
556-0(x)(x)-xx, SMXXXX, SMXXXXX	Vista Brite tip / Envoy	JL Family, AL Family, XB Left Family, JR Family
556-1(x)(x)-xx, SMXXXX, SMXXXXX	"	Right Superior Take Off, AR Family, Other Right Family, XBR Family, Left/Right Coronary Bypass
556-2(x)(x)-xx, SMXXXX, SMXXXXX	"	Endovascular / Radiology / Peripherals
	<u>Multivessel Shapes</u>	
556-27(x)-xx, SMXXXX, SMXXXXX		Multipurpose Family
556-27(x)-xx, SMXXXX, SMXXXXX		Hockey Stick Family
556-28(x)-xx, SMXXXX, SMXXXXX		Straight Family

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Certificate History

Date	Reference Number	Action
3 January 1996	MD 000065	First Issue
3 September 1996	MD 000143	All products present in the scope except for the Envoy have had a line extension to provide catheters with longer lengths
26 June 1997	MD 000242	Change of Body material and lengths of the 5F and 6F ENVOY and 6F, 7F, and 8F Vista Brite Tip Catheters. Inclusion of the ECO package (5 single pouched catheters in a box)
30 June 1997	MD 000242	Amendment to 10F Vista Brite tip catalogue number to read 511-XXXOXXT
19 December 1997	MD 000272	4.7F and 6F Eco-packs; 6F and 8F Long Brite Tip products added to the product listing

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Date	Reference Number	Action
1 May 1998	MD 000395	620-5F SMXXXX, SMXXXXX Envoy 620-6F SMXXXX, SMXXXXX Envoy 562-6F SMXXXX, SMXXXXX Petit Brite Tip TM Vista 564-6F SMXXXX, SMXXXXX Vista Brite Tip 572-7F SMXXXX, SMXXXXX Brite Tip 574-7F SMXXXX, SMXXXXX Vista Brite Tip TM Vista 578-8F SMXXXX, SMXXXXX Brite Tip 584-8F SMXXXX, SMXXXXX XL Brite Tip 586-8F SMXXXX, SMXXXXX Vista Brite Tip 598-9F SMXXXX, SMXXXXX Vista Brite Tip 511-10F SMXXXX, SMXXXXX Vista Brite Tip 523-4.7F SMXXXX, SMXXXXX ECO packs 564-4.7F and 6F SMXXXX, SMXXXXX ECO packs 564-6F SMXXXX, SMXXXXX Long Brite Tip 588-8F SMXXXX, SMXXXXX Vista Brite Tip Added to the product range

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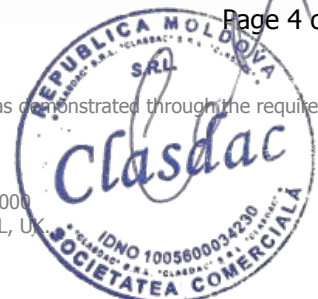
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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK
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Date	Reference Number	Action
3 June 1998	MD 000403	562-6F SMXXXX, SMXXXX Petit Brite Tip TM 564-6F 6MBLC, 6MBRC, 6MA, 6MB, 6MC, 6MD, 6ME, 6LAD3, 6LAD3.5, 6LAD 4 Vista Brite Tip TM Vista 788-7F XXX-XX, XXX-XE, SMXXXX, SMXXXX Vista Brite Tip Added to the product listing. 564-6F 6XXX, Vista Brite Tip and Envoy deleted from the product listing
16 September 1998	MD 000464	667-6F XXX_XX, XXX-XE Vista Brite Tip 620-6F XXX-XX, XXX-XE SMXXXX, SMXXXX Vista Brite Tip Added to the product listing
23 March 1999	MD 000558	Scope changed to read: "Cordis Guiding catheters and Introducing Catheters" 523-050-5F SMXXXX, SMXXXX Eco Pack 677-5F and 6F XXX-XN, SMXXXX, XMXXXX Eco pack Added to the product listing
23 June 1999	MD 000558	667-XXX-XL – 6F Long Brite Tip 588-8XX-8F long Brite Tip Added to the product range

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11 May 2000	10011849	Guiding Catheter 5F range added to the product listing 556-37 (X) – XX Multipurpose Family 556-27 (X) –XX Hockey Stick Family 556-28 (X) – XX Straight Family Added to the product listing
3 January 2001	10020673	5 year Renewal
29 November 2001	10032354	SMXXXX, SMXXXXX sizes added to the 5F Guiding Catheter and Multivessel shape product range
10 October 2002	10042512	Change catalogue numbers from 511-OXX to 511-XXXX
31 March 2006	10078108	5 Year Renewal, change scope, remove eco packs and introducing catheters
08 June 2007	10088941	Change in pouch heat seal coating from CR 27 (ex. Perfecseal) and 703 HSC (ex. Mangar) to PTH 025 (ex. Mangar)
01 August 2007	10089895	Add pouch with RLE004 PET/PE film PTH 034 heat seal coating, and Tyvek 1073B
07 December 2010	10119347	Certificate Renewal
13 December 2015	10159051	Certificate renewal and Envoy Interventional Neuro-Radiology product codes removed from scope – transferred to Codman & Shurtleff Inc. certificate CE 555760.

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