

EC Design-Examination Certificate

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

No. **CE 629250**
Issued To: **Abbott Vascular**
3200 Lakeside Drive
Santa Clara
California
95054
USA

In respect of:

MULTI-LINK 8 SV Coronary Stent Systems, MULTI-LINK 8 Coronary Stent Systems, MULTI-LINK 8 LL Coronary Stent Systems

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: **05 February 2015**

Date: **12 January 2016**

Expiry Date: **17 December 2019**

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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 629250

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MULTI-LINK 8 SV Coronary Stent System					
Model Number	Stent dimensions (mm)		Model Number	Stent dimensions (mm)	
	Diameter	Length		Diameter	Length
1012164-08	2.25	8	1012164-18	2.25	18
1012164-12	2.25	12	1012164-23	2.25	23
1012164-15	2.25	15	1012164-28	2.25	28

MULTI-LINK 8 Coronary Stent System					
Model Number	Stent dimensions (mm)		Model Number	Stent dimensions (mm)	
	Diameter	Length		Diameter	Length
1012165-08	2.5	8	1012167-18	3.0	18
1012165-12	2.5	12	1012167-23	3.0	23
1012165-15	2.5	15	1012167-28	3.0	28
1012165-18	2.5	18	1012168-08	3.5	8
1012165-23	2.5	23	1012168-12	3.5	12
1012165-28	2.5	28	1012168-15	3.5	15
1012166-08	2.75	8	1012168-18	3.5	18
1012166-12	2.75	12	1012168-23	3.5	23
1012166-15	2.75	15	1012168-28	3.5	28
1012166-18	2.75	18	1012169-08	4.0	8
1012166-23	2.75	23	1012169-12	4.0	12
1012166-28	2.75	28	1012169-15	4.0	15
1012167-08	3.0	8	1012169-18	4.0	18
1012167-12	3.0	12	1012169-23	4.0	23
1012167-15	3.0	15	1012169-28	4.0	28

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MULTI-LINK 8 LL Coronary Stent System					
Model Number	Stent dimensions (mm)		Model Number	Stent dimensions (mm)	
	Diameter	Length		Diameter	Length
1012165-33	2.5	33	1012167-38	3.0	38
1012165-38	2.5	38	1012168-33	3.5	33
1012166-33	2.75	33	1012168-38	3.5	38
1012166-38	2.75	38	1012169-33	4.0	33
1012167-33	3.0	33	1012169-38	4.0	38

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Certificate History

Date	Reference Number	Action
05 February 2015	10153170	New Issue. Transfer from another Notified Body.
13 May 2015	10155215	Introduction of electronic IFUs in compliance with Regulation 207/2012.
12 January 2016	10159718	DuPont Tyvek Medical Transition Project update.

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