Abbott Vascular

3200 Lakeside Drive
Santa Clara, CA 95054

Tel 408-845-3000
Fax 408-845-3333

DECLARATION OF CONFORMITY

Manufacturer:	Abbott Vascular
Addresses:	3200 Lakeside Drive Santa Clara, CA 95054 USA
Additional Manufacturing Sites:	26531 Ynez Road Temecula, CA 92591 USA Cashel Road Clonmel, County Tipperary, Ireland
Device Name:	**MULTI-LINK 8 Coronary Stent System** **MULTI-LINK 8 LL Coronary Stent System** **MULTI-LINK 8 SV Coronary Stent System**
Device Classification:	Class III
GMDN Code:	53616 – Bare metal and coronary artery stent
Classification Rationale:	The following Annex IX definition(s) apply to the **MULTI-LINK 8, MULTI-LINK 8 LL and MULTI-LINK 8 SV Coronary Stent Systems** for purposes of classifications: Per Rule 8, Annex IX, all surgically invasive devices to be used in direct contact with the heart, the central circulatory system or the central nervous system are in Class III.
Authorized European Representative:	Abbott Vascular International BVBA Park Lane, Culliganlaan 2B 1831 Diegem, Belgium

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Model Numbers:

MULTI-LINK 8 Coronary Stent System Model Numbers	Stent dimensions		MULTI-LINK 8 Coronary Stent System Model Numbers	Stent dimensions	
	Diameter (mm)	Length (mm)		Diameter (mm)	Length (mm)
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

MULTI-LINK 8 LL Coronary Stent System Model Numbers	Stent dimensions		MULTI-LINK 8 LL Coronary Stent System Model Number	Stent dimensions	
	Diameter (mm)	Length (mm)		Diameter (mm)	Length (mm)
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

MULTI-LINK 8 SV Coronary Stent System Model Numbers	Stent dimensions		MULTI-LINK 8 SV Coronary Stent System Model Numbers	Stent dimensions	
	Diameter (mm)	Length (mm)		Diameter (mm)	Length (mm)
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

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I, the undersigned, hereby declare that the medical devices specified above conform with the applicable *Essential Requirements* listed in Annex I and Annex II of EC Council Directive 93/42/EEC, including all amendments.

Directive 2006/42/EC on Machinery and directive 1989/686/EC on Personal Protective Equipment do not apply.

This declaration is supported by an EC quality system (Annex II) and design examination certification listed below.

Supporting Certificates:
EC Quality Management System, EN ISO 13485:2012 + AC:2012 Certificate Number: FM 72377
EC Design Examination Certificate Number: CE 629250
Annex II Certificate Number: CE 510108

Notified Body:
BSI
Kitemark Court
Davy Avenue
Knowlhill, Milton Keynes
MK5 8PP United Kingdom
Notified Body Identification Number: 0086.

This Declaration of Conformity is valid until revision or with the obsolescence of any of the supporting CE certificates listed above.

This Declaration of Conformity is valid for the model numbers listed that were manufactured on or after February 5, 2015. The Declaration is also valid for rework activities executed after the date of effectivity for lots previously manufactured.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

By: Susan Slane Date: 2/5/2015
Susan Slane,
Divisional VP, Quality, Compliance, and Analytical Chemistry

Place of issue: Santa Clara, CA Date of issue: 2/5/2015

Effective Date: February 5, 2015