Abbott Vascular

3200 Lakeside Drive
Santa Clara, CA 95054

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

DECLARATION OF CONFORMITY

Manufacturer:	Abbott Vascular
Address:	3200 Lakeside Drive Santa Clara, California 95054, USA
Additional Manufacturing Sites:	Cashel Road Clonmel, Co., Tipperary, Ireland
Device Name:	**OMNILINK ELITE Peripheral Stent System**
Device Classification:	Class IIb
GMDN Code:	47932 - Multiple peripheral artery stent
Classification Rationale:	The following Annex IX definition(s) apply to the **OMNILINK ELITE Peripheral Stent System** for purposes of classification: Per Rule 8, Annex IX, all implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended: to be used in direct contact with the heart, the central circulatory system, or the central nervous system, in which case they are in Class III.
Authorized European Representative:	Abbott Vascular International BVBA Park Lane, Culliganlaan 2B 1831 Diegem, Belgium

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Model Numbers: **OMNILINK ELITE Peripheral Stent System**

Useable length 80 cm						
	Nominal Stent Length (mm)					
Balloon diameter (mm)	12	16	19	29	39	59
4	11000-12	11000-16	11000-19	---	---	---
5	11001-12	11001-16	11001-19	11001-29	11001-39	11001-59
6	11002-12	11002-16	11002-19	11002-29	11002-39	11002-59
7	11003-12	11003-16	11003-19	11003-29	11003-39	11003-59
8	---	---	11004-19	11004-29	11004-39	11004-59
9	---	---	11005-19	11005-29	11005-39	11005-59
10	---	---	11006-19	11006-29	11006-39	11006-59

Uscable length 135 cm						
	Nominal Stent Length (mm)					
Balloon diameter (mm)	12	16	19	29	39	59
4	11007-12	11007-16	11007-19	---	---	---
5	11008-12	11008-16	11008-19	11008-29	11008-39	11008-59
6	11009-12	11009-16	11009-19	11009-29	11009-39	11009-59
7	11010-12	11010-16	11010-19	11010-29	11010-39	11010-59
8	---	---	11011-19	11011-29	11011-39	11011-59
9	---	---	11012-19	11012-29	11012-39	11012-59
10	---	---	11013-19	11013-29	11013-39	11013-59

I, the undersigned, hereby declare that the medical devices specified above conform with the applicable *Essential Requirements* listed in Annex I and Annex II (except Part 4) of EC Council Directive 93/42/EEC.

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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 certification listed below.

Supporting Certificates:
EC Quality Management System, ISO 13485:2003 Certificate Number: FM 72377
Annex II Certificate Number: CE 510108

Notified Body: British Standards Institution
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes
MK5 8PP
United Kingdom
Notified Body Identification Number: 0086

This Declaration of Conformity is valid until its revision or with the obsolescence of the supporting Annex II certificate listed above.

The below listed signature section is applicable to all DoC documents:

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

Authorized Signatory: _____
Aruna Akkapeddi, Sr. RA Specialist

Issued By: _____
Susan Slane, Divisional VP, Global Quality & Compliance
Abbott Vascular

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.
Place of issue: Temecula Date of issue: 1/19/2016

Effective Date: 1/19/2016