Abbott Vascular

3200 Lakeside Drive
Santa Clara, CA 95054

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

DECLARATION OF CONFORMITY

Manufacturer:	Abbott Vascular
Addresses:	Abbott Vascular 3200 Lakeside Drive Santa Clara, California 95054 USA
Additional Manufacturing Sites:	Abbott Vascular 26531 Ynez Road Temecula California 92591 USA
Device Name:	Supera Peripheral Stent System
Device Classification:	IIb
GMDN Code:	47932, Multiple peripheral artery stent, bare-metal.
Classification Rationale:	The following Annex IX definition(s) apply to the Supera Peripheral Stent System for the purposes of classification: Per Rule 8 Annex IX: 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, the central nervous system or to administer medications, 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:

Model No.	Stent Diameter	Stent Length	Catheter Length	Catheter Fr Size
SE-04-020-080-6F	4mm	20mm	80cm	6Fr
SE-04-030-080-6F	4mm	30mm	80cm	6Fr
SE-04-040-080-6F	4mm	40mm	80cm	6Fr
SE-04-060-080-6F	4mm	60mm	80cm	6Fr
SE-04-080-080-6F	4mm	80mm	80cm	6Fr
SE-04-100-080-6F	4mm	100mm	80cm	6Fr
SE-04-120-080-6F	4mm	120mm	80cm	6Fr
SE-04-150-080-6F	4mm	150mm	80cm	6Fr
SE-05-020-080-6F	5mm	20mm	80cm	6Fr
SE-05-030-080-6F	5mm	30mm	80cm	6Fr
SE-05-040-080-6F	5mm	40mm	80cm	6Fr
SE-05-060-080-6F	5mm	60mm	80cm	6Fr
SE-05-080-080-6F	5mm	80mm	80cm	6Fr
SE-05-100-080-6F	5mm	100mm	80cm	6Fr
SE-05-120-080-6F	5mm	120mm	80cm	6Fr
SE-05-150-080-6F	5mm	150mm	80cm	6Fr
SE-05-180-080-6F	5mm	180mm	80cm	6Fr
SE-05-200-080-6F	5mm	200mm	80cm	6Fr
SE-06-020-080-6F	6mm	20mm	80cm	6Fr
SE-06-030-080-6F	6mm	30mm	80cm	6Fr
SE-06-040-080-6F	6mm	40mm	80cm	6Fr
SE-06-060-080-6F	6mm	60mm	80cm	6Fr
SE-06-080-080-6F	6mm	80mm	80cm	6Fr
SE-06-100-080-6F	6mm	100mm	80cm	6Fr
SE-06-120-080-6F	6mm	120mm	80cm	6Fr
SE-06-150-080-6F	6mm	150mm	80cm	6Fr
SE-06-180-080-6F	6mm	180mm	80cm	6Fr
SE-06-200-080-6F	6mm	200mm	80cm	6Fr
SE-07-020-080-6F	7mm	20mm	80cm	6Fr
SE-07-030-080-6F	7mm	30mm	80cm	6Fr
SE-07-040-080-6F	7mm	40mm	80cm	6Fr
SE-07-060-080-6F	7mm	60mm	80cm	6Fr
SE-07-080-080-6F	7mm	80mm	80cm	6Fr
SE-07-100-080-6F	7mm	100mm	80cm	6Fr
SE-04-020-120-6F	4mm	20mm	120cm	6Fr
SE-04-030-120-6F	4mm	30mm	120cm	6Fr
SE-04-040-120-6F	4mm	40mm	120cm	6Fr
SE-04-060-120-6F	4mm	60mm	120cm	6Fr
SE-04-080-120-6F	4mm	80mm	120cm	6Fr
SE-04-100-120-6F	4mm	100mm	120cm	6Fr
SE-04-120-120-6F	4mm	120mm	120cm	6Fr
SE-04-150-120-6F	4mm	150mm	120cm	6Fr
SE-05-020-120-6F	5mm	20mm	120cm	6Fr
SE-05-030-120-6F	5mm	30mm	120cm	6Fr
SE-05-040-120-6F	5mm	40mm	120cm	6Fr
SE-05-060-120-6F	5mm	60mm	120cm	6Fr
SE-05-080-120-6F	5mm	80mm	120cm	6Fr
SE-05-100-120-6F	5mm	100mm	120cm	6Fr
SE-05-120-120-6F	5mm	120mm	120cm	6Fr
SE-05-150-120-6F	5mm	150mm	120cm	6Fr

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Model No.	Stent Diameter	Stent Length	Catheter Length	Catheter Fr Size
SE-05-180-120-6F	5mm	180mm	120cm	6Fr
SE-05-200-120-6F	5mm	200mm	120cm	6Fr
SE-06-020-120-6F	6mm	20mm	120cm	6Fr
SE-06-030-120-6F	6mm	30mm	120cm	6Fr
SE-06-040-120-6F	6mm	40mm	120cm	6Fr
SE-06-060-120-6F	6mm	60mm	120cm	6Fr
SE-06-080-120-6F	6mm	80mm	120cm	6Fr
SE-06-100-120-6F	6mm	100mm	120cm	6Fr
SE-06-120-120-6F	6mm	120mm	120cm	6Fr
SE-06-150-120-6F	6mm	150mm	120cm	6Fr
SE-06-180-120-6F	6mm	180mm	120cm	6Fr
SE-06-200-120-6F	6mm	200mm	120cm	6Fr
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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 Part 3 of EC Council Directive 93/42/EEC.

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 and theAnnex II (except Part 4) certificate 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 revision or with the obsolescence of the supporting Annex II certificate listed above.

This Declaration is applicable to all lots of Supera Peripheral Stent Systems placed on the market on or after September 2, 2014 that are manufactured by Abbott Vascular at the Temecula, California manufacturing site.

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

By: Sy Slane 9/18/15
Susan Slane,
Divisional VP, Quality, Compliance, and Analytical Chemistry

Place of issue: Temecula Date of issue: 9/18/15

Effective Date: 9/18/15