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:	Xpert Pro Peripheral Self-Expanding 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 Xpert Pro Peripheral Self-Expanding Stent System for the purposes of classification: Per Rule 8 Annex IX: All implantable devices and long-term surgically invasive devices are in Class IIb. The Xpert Pro Peripheral Self Expanding Stent System is not intended to be used in direct contact with the heart or the central circulatory system or to administer medications.
Authorized European Representative:	Abbott Vascular International BVBA Park Lane, Culliganiaan 2B 1831 Diegem, Belgium

Model Numbers:

Device Model Numbers of 80 / 90 cm usable catheter length

	Nominal stent length [mm]					
Nominal stent diameter [mm]	**20**	**30**	**40**	**60**	**80**	**100**
3	17525-20	17525-30	17525-40	17525-60	17525-80	17525-100
4	17526-20	17526-30	17526-40	17526-60	17526-80	17526-100
5	17527-20	17527-30	17527-40	17527-60	17527-80	17527-100
6	17528-20	17528-30	17528-40	17528-60	17528-80	Not Available
8	Not Available	17529-30	17529-40	17529-60	Not Available	Not Available

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Device Model Numbers of 120 / 135 cm usable catheter length

	Nominal stent length [mm]					
Nominal stent diameter [mm]	**20**	**30**	**40**	**60**	**80**	**100**
3	17538-20	17538-30	17538-40	17538-60	17538-80	17538-100
4	17539-20	17539-30	17539-40	17539-60	17539-80	17539-100
5	17540-20	17540-30	17540-40	17540-60	17540-80	17540-100
6	17541-20	17541-30	17541-40	17541-60	17541-80	Not Available
8	Not Available	17542-30	17542-40	17542-60	Not Available	Not Available

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 (Annex II, except Prat 4) 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 – Identification Number 0086
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes
MK5 8PP
United Kingdom

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

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

By: _____
Susan Slane,
Divisional VP, Quality, Compliance, and Analytical Chemistry

Place of issue: Temecula Date of issue: 10/21/15

Effective Date: 10/21/15