Abbott

3200 Lakeside Drive
Santa Clara, CA 95054, USA
Tel: 001-408-845-3000
Fax: 001-408-845-3333

DECLARATION OF CONFORMITY

Manufacturer:	Abbott Vascular
Address:	3200 Lakeside Drive Santa Clara, California 95054 USA
Manufacturing Site(s):	Abbott Vascular 26531 Ynez Road Temecula, California 92591 USA Abbott Vascular Cashel Road Clonmel, Tipperary, Ireland
Device Name:	**XIENCE PRO Everolimus Eluting Coronary and Peripheral Stent Systems (Includes XIENCE PRO, XIENCE PRO^{X}, XIENCE PRO^{A} and XIENCE PRO 48)**
Device Classification:	Class III
GMDN Code:	56284 – Drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated
Classification Rationale:	The following Annex IX definition(s) apply to the **XIENCE PRO Everolimus Eluting Coronary and Peripheral Stent Systems** consisting of XIENCE PRO, XIENCE PRO^{X}, XIENCE PRO^{A} and XIENCE PRO 48 EECSS indicated for improving coronary luminal diameter. For purposes of classifications: Per Rule 8, Annex IX, all implantable devices to be used in direct contact with the heart, the central circulatory system or the central nervous system are in Class III. Per Rule 13 of Annex IX, all devices incorporating, as an integral part, a substance which, if used separately, can be considered a medicinal product, and which is liable to act on the human body with action ancillary to that of the device, are in Class III.
Authorized European Representative:	Abbott Vascular International BVBA Park Lane, Culliganlaan 2B 1831 Diegem, Belgium

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Model Numbers:

Device Name	Stent Diameter (mm)	Stent Length (mm)	Model Number
XIENCE PRO Everolimus Eluting Coronary Stent System	2.25	8	1017225-08
	2.25	12	1017225-12
	2.25	15	1017225-15
	2.25	18	1017225-18
	2.25	23	1017225-23
	2.25	28	1017225-28
	2.50	8	1017250-08
	2.50	12	1017250-12
	2.50	15	1017250-15
	2.50	18	1017250-18
	2.50	23	1017250-23
	2.50	28	1017250-28
	2.75	8	1017275-08
	2.75	12	1017275-12
	2.75	15	1017275-15
	2.75	18	1017275-18
	2.75	23	1017275-23
	2.75	28	1017275-28
	3.0	8	1017300-08
	3.0	12	1017300-12
	3.0	15	1017300-15
	3.0	18	1017300-18
	3.0	23	1017300-23
	3.0	28	1017300-28
	3.50	8	1017350-08
	3.50	12	1017350-12
	3.50	15	1017350-15
	3.50	18	1017350-18
	3.50	23	1017350-23
	3.50	28	1017350-28
	4.0	8	1017400-08
	4.0	12	1017400-12
	4.0	15	1017400-15
	4.0	18	1017400-18
	4.0	23	1017400-23
	4.0	28	1017400-28
XIENCE PRO X	2.0	8	1076200-08
	2.0	12	1076200-12

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Device Name	Stent Diameter (mm)	Stent Length (mm)	Model Number
Everolimus Eluting Coronary Stent System	2.0	15	1076200-15
	2.0	18	1076200-18
	2.0	23	1076200-23
	2.0	28	1076200-28
	2.25	8	1076225-08
	2.25	12	1076225-12
	2.25	15	1076225-15
	2.25	18	1076225-18
	2.25	23	1076225-23
	2.25	28	1076225-28
	2.50	8	1076250-08
	2.50	12	1076250-12
	2.50	15	1076250-15
	2.50	18	1076250-18
	2.50	23	1076250-23
	2.50	28	1076250-28
	2.50	33	1076250-33
	2.50	38	1076250-38
	2.75	8	1076275-08
	2.75	12	1076275-12
	2.75	15	1076275-15
	2.75	18	1076275-18
	2.75	23	1076275-23
	2.75	28	1076275-28
	2.75	33	1076275-33
	2.75	38	1076275-38
	3.0	8	1076300-08
	3.0	12	1076300-12
	3.0	15	1076300-15
	3.0	18	1076300-18
	3.0	23	1076300-23
	3.0	28	1076300-28
	3.0	33	1076300-33
	3.0	38	1076300-38
	3.25	8	1076325-08
	3.25	12	1076325-12
	3.25	15	1076325-15
	3.25	18	1076325-18
	3.25	23	1076325-23
	3.25	28	1076325-28

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Device Name	Stent Diameter (mm)	Stent Length (mm)	Model Number
	3.25	33	1076325-33
	3.25	38	1076325-38
	3.50	8	1076350-08
	3.50	12	1076350-12
	3.50	15	1076350-15
	3.50	18	1076350-18
	3.50	23	1076350-23
	3.50	28	1076350-28
	3.50	33	1076350-33
	3.50	38	1076350-38
	4.0	8	1076400-08
	4.0	12	1076400-12
	4.0	15	1076400-15
	4.0	18	1076400-18
	4.0	23	1076400-23
	4.0	28	1076400-28
	4.0	33	1076400-33
	4.0	38	1076400-38
XIENCE PRO 48 Everolimus Eluting Coronary Stent System	2.50	48	1017250-48
	2.75	48	1017275-48
	3.0	48	1017300-48
	3.5	48	1017350-48
XIENCE PRO[A] Everolimus Eluting Coronary Stent System	2.0	8	1128200-08
	2.0	12	1128200-12
	2.0	15	1128200-15
	2.0	18	1128200-18
	2.0	23	1128200-23
	2.0	28	1128200-28
	2.25	8	1128225-08
	2.25	12	1128225-12
	2.25	15	1128225-15
	2.25	18	1128225-18
	2.25	23	1128225-23
	2.25	28	1128225-28
	2.5	8	1128250-08
	2.5	12	1128250-12
	2.5	15	1128250-15
	2.5	18	1128250-18
	2.5	23	1128250-23
	2.5	28	1128250-28

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Device Name	Stent Diameter (mm)	Stent Length (mm)	Model Number
	2.5	33	1128250-33
	2.5	38	1128250-38
	2.75	8	1128275-08
	2.75	12	1128275-12
	2.75	15	1128275-15
	2.75	18	1128275-18
	2.75	23	1128275-23
	2.75	28	1128275-28
	2.75	33	1128275-33
	2.75	38	1128275-38
	3.0	8	1128300-08
	3.0	12	1128300-12
	3.0	15	1128300-15
	3.0	18	1128300-18
	3.0	23	1128300-23
	3.0	28	1128300-28
	3.0	33	1128300-33
	3.0	38	1128300-38
	3.25	8	1128325-08
	3.25	12	1128325-12
	3.25	15	1128325-15
	3.25	18	1128325-18
	3.25	23	1128325-23
	3.25	28	1128325-28
	3.25	33	1128325-33
	3.25	38	1128325-38
	3.5	8	1128350-08
	3.5	12	1128350-12
	3.5	15	1128350-15
	3.5	18	1128350-18
	3.5	23	1128350-23
	3.5	28	1128350-28
	3.5	33	1128350-33
	3.5	38	1128350-38
	4.0	8	1128400-08
	4.0	12	1128400-12
	4.0	15	1128400-15
	4.0	18	1128400-18
	4.0	23	1128400-23
	4.0	28	1128400-28

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Device Name	Stent Diameter (mm)	Stent Length (mm)	Model Number
	4.0	33	1128400-33
	4.0	38	1128400-38

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.

Directive 2006/42/EC on Machinery and directive 89/686/EEC 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: ISO13485:2016
Certificate Number: FM 72377

EC Design Examination
Certificate Number: CE 632827

Annex II Certificate Number: CE 510108

Notified Body: BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
Netherlands
Notified Body Identification Number: 2797

This Declaration of Conformity is valid until its revision, or with the obsolescence of the supporting Annex II and EC Design Examination certificates listed above.

This Declaration of Conformity is valid for the model numbers listed that were manufactured on or after April 13, 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.

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Authorized Signatory: _____
Fiona Pu
Senior Regulatory Affairs Specialist
Abbott Vascular

Issued By: _____
Julie Manalili,
Senior Director Quality Operations and Compliance
Abbott Vascular

Place of issue: Temecula Date of issue: 3/1/2019

Effective Date: February 27, 2019