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, CA 95054 USA

Additional Manufacturing Sites:
Abbott Vascular
26531 Ynez Road
Temecula, CA 92591 USA

Abbott Vascular
42301 Zevo Drive
Temecula, CA 92590 USA

Abbott Vascular
Cashel Road
Clonmel, County Tipperary, Ireland

Abbott Vascular
52 Calle 3, B31
Coyol Free Zone
El Coyol Alajuela, Costa Rica
NOTE: Only XIENCE PRO^X is approved for this site

Device Name: **XIENCE PRO Everolimus Eluting Coronary Stent System (includes XIENCE PRO, XIENCE PRO LL, XIENCE PRO^X and XIENCE PRO 48)**

Device Classification: Class III

GMDN Code: 56284 – Drug-eluting coronary artery stent, non-biodegradable-polymer-coated

46919 – Peripheral artery stent, drug-eluting (XIENCE PRO LL)

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Classification Rationale: The following Annex IX definition(s) applies to the **XIENCE PRO Everolimus Eluting Coronary Stent System** (consisting of **XIENCE PRO, XIENCE PRO LL, XIENCE PRO^{X} and XIENCE PRO 48 EECSS**) indicated for improving coronary luminal diameter and **XIENCE PRO LL Everolimus Eluting Coronary Stent System** indicated for improving peripheral luminal diameter for purposes of classification: 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:

XIENCE PRO EECSS:

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
	2.5	8	1017250-08
	2.5	12	1017250-12
	2.5	15	1017250-15
	2.5	18	1017250-18
	2.5	23	1017250-23
	2.5	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
	3.5	8	1017350-08
	3.5	12	1017350-12
	3.5	15	1017350-15
	3.5	18	1017350-18
	3.5	23	1017350-23
	3.5	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

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XIENCE PRO LL EECSS:

Device Name	Stent Diameter (mm)	Stent Length (mm)	Model Number
XIENCE PRO LL Everolimus Eluting Coronary Stent System	2.5	33	1017250-33
	2.5	38	1017250-38
	2.75	33	1017275-33
	2.75	38	1017275-38
	3.0	33	1017300-33
	3.0	38	1017300-38
	3.5	33	1017350-33
	3.5	38	1017350-38
	4.0	33	1017400-33
	4.0	38	1017400-38

XIENCE PRO^{X} EECSS:

Device Name	Stent Diameter (mm)	Stent Length (mm)	Model Number
XIENCE PRO^{X} Everolimus Eluting Coronary Stent System	2.0	08	1076200-08
	2.0	12	1076200-12
	2.0	15	1076200-15
	2.0	18	1076200-18
	2.0	23	1076200-23
	2.0	28	1076200-28
	2.25	08	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
	2.5	08	1076250-08
	2.5	12	1076250-12
	2.5	15	1076250-15
	2.5	18	1076250-18
	2.5	23	1076250-23
	2.5	28	1076250-28
	2.5	33	1076250-33
	2.5	38	1076250-38
	2.75	08	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

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Device Name	Stent Diameter (mm)	Stent Length (mm)	Model Number
	2.75	33	1076275-33
	2.75	38	1076275-38
	3.0	08	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	08	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
	3.25	33	1076325-33
	3.25	38	1076325-38
	3.5	08	1076350-08
	3.5	12	1076350-12
	3.5	15	1076350-15
	3.5	18	1076350-18
	3.5	23	1076350-23
	3.5	28	1076350-28
	3.5	33	1076350-33
	3.5	38	1076350-38
	4.0	08	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

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XIENCE PRO 48 EECSS:

Device Name	Stent Diameter (mm)	Stent Length (mm)	Model Number
XIENCE PRO 48 Everolimus Eluting Coronary Stent System	2.5	48	1017250-48
	2.75	48	1017275-48
	3.0	48	1017300-48
	3.5	48	1017350-48

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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 of June 1993, including all amendments. This declaration is supported by an EC quality system and design examination approval (Annex II) listed below.

Supporting Certificates:
EC Quality Management System, ISO 13485:2003 Certificate Number: 3803730
EC Design Examination Certificate Number: 3803730DE03
Annex II Certificate Number: 3803730CE02

Notified Body:
DEKRA Certification B.V., Arnhem, The Netherlands
Notified Body Identification Number 0344

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

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

By: S Slane Date: 3/27/14

Susan Slane
Divisional VP, Global Quality and Compliance
Abbott Vascular

By: V Swassing Date: 3/31/2014

V.A. Swassing
Director, Regulatory Affairs
Abbott Vascular

Place of issue: Santa Clara, CA Date of issue: 3/31/2014

Effective Date: 3/31/2014