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[A] Everolimus Eluting Coronary Stent Systems**
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[A] Everolimus Eluting Coronary Stent Systems** 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[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
	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

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Device Name	Stent Diameter (mm)	Stent Length (mm)	Model Number
XIENCE PRO[A] Everolimus Eluting Coronary Stent System	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
	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: FM72377
EC Design Examination Certificate Number: CE 632827
Annex II Certificate Number: CE 510108

REPUBLICA MOLDOVA S.R.L. Clasdac IDNO 1005600034230 SOCIETATEA COMERCIALĂ

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Notified Body:
BSI
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 and EC Design Examination certificates listed above.

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

Authorized Signatory: _____
Michele Walz
Regulatory Affairs Project Manager
Abbott Vascular

Issued by: _____
Pauline Hanley
Senior Director, Quality Operations and Compliance
Abbott Vascular

Place of issue: Temecula Date of issue: March 06, 2018

Effective Date: March 06, 208

Version #1.0

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Delegation or Proxy Template

Will this delegation memo be used to obtain signatures from a business partner who does not have access to the Abbott Vascular Quality System or applications? ☒ NO

Signature Delegation

This memo delegates my signature authority to: Pauline Hanley

Scope of delegation authority includes: Declaration of Conformity for Sierra & Xience PROA

Delegation begins on: 06 March, 2018

Delegation ends on: 09 March, 2018

Name: Steven Eldridge

Title: DVP Global Quality and Compliance

Signature:

Date: 06 March, 2018

Attach this evidence of delegation to all records being approved.

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