



Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. CE 632827

Issued To: Abbott Vascular

3200 Lakeside Drive

Santa Clara California 95054 USA

In respect of:

**XIENCE PRO Everolimus-eluting Coronary and Peripheral Stent Systems** 

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk -

**Medical Devices** 

First Issued: **2015-04-13** Date: **2018-03-05** Expiry Date: **2021-12-01** 

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.





### **Supplementary Information to CE 632827**

Issued To: Abbott Vascular

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Santa Clara California 95054 USA

### **XIENCE PRO (Coronary Only)**

First Issued: 2015-04-13

Size	Model Number
2.25 x 8 mm	1017225-08
2.25 x 12 mm	1017225-12
2.25 x 15 mm	1017225-15
2.25 x 18 mm	1017225-18
2.25 x 23 mm	1017225-23
2.25 x 28 mm	1017225-28
2.50 x 8 mm	1017250-08
2.50 x 12 mm	1017250-12
2.50 x 15 mm	1017250-15
2.50 x 18 mm	1017250-18
2.50 x 23 mm	1017250-23
2.50 x 28 mm	1017250-28
2.75 x 8 mm	1017275-08
2.75 x 12 mm	1017275-12
2.75 x 15 mm	1017275-15
2.75 x 18 mm	1017275-18

Expiry Date: **2021-12-01** 

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Date: 2018-03-05

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of BSI Group of Companies.





#### **Supplementary Information to CE 632827**

Issued To: Abbott Vascular

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## **XIENCE PRO (Coronary Only) (continued)**

Size	Model Number
2.75 x 23 mm	1017275-23
2.75 x 28 mm	1017275-28
3.0 x 8 mm	1017300-08
3.0 x 12 mm	1017300-12
3.0 x 15 mm	1017300-15
3.0 x 18 mm	1017300-18
3.0 x 23 mm	1017300-23
3.0 x 28 mm	1017300-28
3.50 x 8 mm	1017350-08
3.50 x 12 mm	1017350-12
3.50 x 15 mm	1017350-15
3.50 x 18 mm	1017350-18
3.50 x 23 mm	1017350-23
3.50 x 28 mm	1017350-28
4.0 x 8 mm	1017400-08
4.0 x 12 mm	1017400-12



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#### **Supplementary Information to CE 632827**

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### **XIENCE PRO (Coronary Only) (continued)**

Size	Model Number
4.0 x 15 mm	1017400-15
4.0 x 18 mm	1017400-18
4.0 x 23 mm	1017400-23
4.0 x 28 mm	1017400-28



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## **XIENCE PRO LL (Coronary and Peripheral)**

Size	Model Number
2.50 x 33 mm	1017250-33
2.50 x 38 mm	1017250-38
2.75 x 33 mm	1017275-33
2.75 x 38 mm	1017275-38
3.0 x 33 mm	1017300-33
3.0 x 38 mm	1017300-38
3.50 x 33 mm	1017350-33
3.50 x 38 mm	1017350-38
4.0 x 33 mm	1017400-33
4.0 x 38 mm	1017400-38

#### **XIENCE PRO 48 (Coronary Only)**

Size	Model Number
2.50 x 48mm	1017250-48
2.75 x 48 mm	1017275-48
3.0 x 48 mm	1017300-48
3.5 x 48 mm	1017350-48

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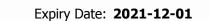
3200 Lakeside Drive

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## **XIENCE PROX** (Coronary Only)

First Issued: 2015-04-13

Size	Model Number
2.0 x 8 mm	1076200-08
2.0 x 12 mm	1076200-12
2.0 x 15 mm	1076200-15
2.0 x 18 mm	1076200-18
2.0 x 23 mm	1076200-23
2.0 x 28 mm	1076200-28
2.25 x 8 mm	1076225-08
2.25 x 12 mm	1076225-12



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#### **Supplementary Information to CE 632827**

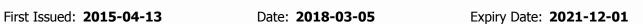
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## **XIENCE PRO<sup>X</sup> (Coronary Only) (continued)**

Size	Model Number
2.25 x 15 mm	1076225-15
2.25 x 18 mm	1076225-18
2.25 x 23 mm	1076225-23
2.25 x 28 mm	1076225-28
2.50 x 8 mm	1076250-08
2.50 x 12 mm	1076250-12
2.50 x 15 mm	1076250-15
2.50 x 18 mm	1076250-18
2.50 x 23 mm	1076250-23
2.50 x 28 mm	1076250-28
2.50 x 33 mm	1076250-33
2.50 x 38 mm	1076250-38
2.75 x 8 mm	1076275-08
2.75 x 12 mm	1076275-12
2.75 x 15 mm	1076275-15
2.75 x 18 mm	1076275-18



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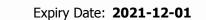
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## **XIENCE PROX** (Coronary Only) (continued)

Size	Model Number
2.75 x 23 mm	1076275-23
2.75 x 28 mm	1076275-28
2.75 x 33 mm	1076275-33
2.75 x 38 mm	1076275-38
3.0 x 8 mm	1076300-08
3.0 x 12 mm	1076300-12
3.0 x 15 mm	1076300-15
3.0 x 18 mm	1076300-18
3.0 x 23 mm	1076300-23
3.0 x 28 mm	1076300-28
3.0 x 33 mm	1076300-33
3.0 x 38 mm	1076300-38



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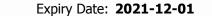
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## **XIENCE PROX** (Coronary Only) (continued)

Size	Model Number
3.25 x 8 mm	1076325-08
3.25 x 12 mm	1076325-12
3.25 x 15 mm	1076325-15
3.25 x 18 mm	1076325-18
3.25 x 23 mm	1076325-23
3.25 x 28 mm	1076325-28
3.25 x 33 mm	1076325-33
3.25 x 38 mm	1076325-38
3.5 x 8 mm	1076350-08
3.5 x 12 mm	1076350-12
3.5 x 15 mm	1076350-15
3.5 x 18 mm	1076350-18



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## **XIENCE PROX** (Coronary Only) (continued)

Size	Model Number
3.5 x 23 mm	1076350-23
3.5 x 28 mm	1076350-28
3.5 x 33 mm	1076350-33
3.5 x 38 mm	1076350-38
4.0 x 8 mm	1076400-08
4.0 x 12 mm	1076400-12
4.0 x 15 mm	1076400-15
4.0 x 18 mm	1076400-18
4.0 x 23 mm	1076400-23
4.0 x 28 mm	1076400-28
4.0 x 33 mm	1076400-33
4.0 x 38 mm	1076400-38



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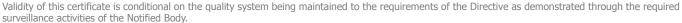
### **XIENCE PRO<sup>A</sup> (Coronary Only) (continued)**

Size	Model Number
2.00 x 8 mm	1128200-08
2.00 x 12 mm	1128200-12
2.00 x 15 mm	1128200-15
2.00 x 18 mm	1128200-18
2.00 x 23 mm	1128200-23
2.00 x 28 mm	1128200-28
2.25 x 8 mm	1128225-08
2.25 x 12 mm	1128225-12
2.25 x 15 mm	1128225-15
2.25 x 18 mm	1128225-18
2.25 x 23 mm	1128225-23
2.25 x 28 mm	1128225-28
2.50 x 08 mm	1128250-08
2.50 x 12 mm	1128250-12
2.50 x 15 mm	1128250-15
2.50 x 18 mm	1128250-18
2.50 x 23 mm	1128250-23
2.50 x 28 mm	1128250-28
2.50 x 33 mm	1128250-33
2.50 x 38 mm	1128250-38

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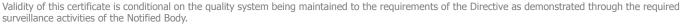
## XIENCE PRO<sup>A</sup> (Coronary Only) (continued)

Size	Model Number
2.75 x 08 mm	1128275-08
2.75 x 12 mm	1128275-12
2.75 x 15 mm	1128275-15
2.75 x 18 mm	1128275-18
2.75 x 23 mm	1128275-23
2.75 x 28 mm	1128275-28
2.75 x 33 mm	1128275-33
2.75 x 38 mm	1128275-38
3.00 x 08 mm	1128300-08
3.00 x 12 mm	1128300-12
3.00 x 15 mm	1128300-15
3.00 x 18 mm	1128300-18
3.00 x 23 mm	1128300-23
3.00 x 28 mm	1128300-28
3.00 x 33 mm	1128300-33
3.00 x 38 mm	1128300-38
3.25 x 8 mm	1128325-08
3.25 x 12 mm	1128325-12
3.25 x 15 mm	1128325-15
3.25 x 18 mm	1128325-18

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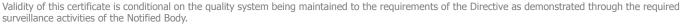
### XIENCE PRO<sup>A</sup> (Coronary Only) (continued)

Size	Model Number
3.25 x 23 mm	1128325-23
3.25 x 28 mm	1128325-28
3.25 x 33 mm	1128325-33
3.25 x 38 mm	1128325-38
3.50 x 08 mm	1128350-08
3.50 x 12 mm	1128350-12
3.50 x 15 mm	1128350-15
3.50 x 18 mm	1128350-18
3.50 x 23 mm	1128350-23
3.50 x 28 mm	1128350-28
3.50 x 33 mm	1128350-33
3.50 x 38 mm	1128350-38
4.00 x 8 mm	1128400-08
4.00 x 12 mm	1128400-12
4.00 x 15 mm	1128400-15
4.00 x 18 mm	1128400-18
4.00 x 23 mm	1128400-23
4.00 x 28 mm	1128400-28
4.00 x 33 mm	1128400-33
4.00 x 38 mm	1128400-38

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## **Certificate History**

Date	Reference Number	Action
13 April 2015	10154362	New Issue. Transfer from another Notified Body.
12 January 2016	10159718	DuPont Tyvek Medical Transition Project update.
24 November 2016	10166114	Certificate Renewal.
10 August 2017	8695169	Various IFU updates including revised risk and clinical use information and alignment of structure and general consistency. Update symbols on labels for consistency across project families.
22 December 2017	8868966	Add Synergy Health in Offaly, Ireland as new ETO sterilization site.
Current	8888512	Addition of product XIENCE PRO <sup>A</sup> as re-branding of the XIENCE Alpine with no design changes.

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