

# EC Design-Examination Certificate

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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Page 1 of 14

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## Supplementary Information to CE 632827

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## XIENCE PRO (Coronary Only)

| 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   |



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Date: **2018-03-05**

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

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Page 2 of 14

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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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Page 3 of 14

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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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Page 4 of 14

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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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Page 5 of 14

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## XIENCE PRO<sup>x</sup> (Coronary Only)

| 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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Page 6 of 14

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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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Page 7 of 14

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## XIENCE PRO<sup>x</sup> (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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Page 8 of 14

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## XIENCE PRO<sup>x</sup> (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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Date: **2018-03-05**

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Page 9 of 14

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## XIENCE PRO<sup>x</sup> (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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Page 10 of 14

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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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Date: **2018-03-05**

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

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Page 11 of 14

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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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Page 12 of 14

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| 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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Page 13 of 14

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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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Page 14 of 14

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