

EC Design-Examination Certificate

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

No. **CE 632826**
Issued To: **Abbott Vascular**
3200 Lakeside Drive
Santa Clara
California
95054
USA

In respect of:

XIENCE Xpedition Everolimus-eluting Coronary 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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **13 April 2015**

Date: **12 January 2016**

Expiry Date: **01 December 2016**

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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.

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

EC Design-Examination Certificate

Supplementary Information to CE 632826

Issued To:

**Abbott Vascular
3200 Lakeside Drive
Santa Clara
California
95054
USA**

XIENCE Xpedition SV

Size	Model Number
2.0 x 8 mm	1070200-08
2.0 x 12 mm	1070200-12
2.0 x 15 mm	1070200-15
2.0 x 18 mm	1070200-18
2.0 x 23 mm	1070200-23
2.0 x 28 mm	1070200-28
2.25 x 8 mm	1070225-08
2.25 x 12 mm	1070225-12
2.25 x 15 mm	1070225-15
2.25 x 18 mm	1070225-18
2.25 x 23 mm	1070225-23
2.25 x 28 mm	1070225-28



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XIENCE Xpedition

Size	Model Number
2.50 x 8 mm	1070250-08
2.50 x 12 mm	1070250-12
2.50 x 15 mm	1070250-15
2.50 x 18 mm	1070250-18
2.50 x 23 mm	1070250-23
2.50 x 28 mm	1070250-28
2.75 x 8 mm	1070275-08
2.75 x 12 mm	1070275-12
2.75 x 15 mm	1070275-15
2.75 x 18 mm	1070275-18
2.75 x 23 mm	1070275-23
2.75 x 28 mm	1070275-28
3.0 x 8 mm	1070300-08
3.0 x 12 mm	1070300-12
3.0 x 15 mm	1070300-15
3.0 x 18 mm	1070300-18



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XIENCE Xpedition (continued)

Size	Model Number
3.0 x 23 mm	1070300-23
3.0 x 28 mm	1070300-28
3.25 x 8 mm	1070325-08
3.25 x 12 mm	1070325-12
3.25 x 15 mm	1070325-15
3.25 x 18 mm	1070325-18
3.25 x 23 mm	1070325-23
3.25 x 28 mm	1070325-28
3.50 x 8 mm	1070350-08
3.50 x 12 mm	1070350-12
3.50 x 15 mm	1070350-15
3.50 x 18 mm	1070350-18
3.50 x 23 mm	1070350-23
3.50 x 28 mm	1070350-28
4.0 x 8 mm	1070400-08
4.0 x 12 mm	1070400-12



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XIENCE Xpedition (continued)

Size	Model Number
4.0 x 15 mm	1070400-15
4.0 x 18 mm	1070400-18
4.0 x 23 mm	1070400-23
4.0 x 28 mm	1070400-28

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XIENCE Xpedition LL

Size	Model Number
2.50 x 33 mm	1070250-33
2.50 x 38 mm	1070250-38
2.75 x 33 mm	1070275-33
2.75 x 38 mm	1070275-38
3.0 x 33 mm	1070300-33
3.0 x 38 mm	1070300-38
3.25 x 33 mm	1070325-33
3.25 x 38 mm	1070325-38
3.50 x 33 mm	1070350-33
3.50 x 38 mm	1070350-38
4.0 x 33 mm	1070400-33
4.0 x 38 mm	1070400-38



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XIENCE Xpedition 48

Size	Model Number
2.50 x 48 mm	1070250-48
2.75 x 48 mm	1070275-48
3.0 x 48 mm	1070300-48
3.5 x 48 mm	1070350-48



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Certificate History

Date	Reference Number	Action
13 April 2015	10154361	New Issue. Transfer from another Notified Body.
12 January 2016	10159718	DuPont Tyvek Medical Transition Project update.

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