Abbott Vascular

3200 Lakeside Drive
Santa Clara, CA 95054

Tel: 408-845-3000
Fax: 408-845-3333

# DECLARATION OF CONFORMITY

| | |
|---|---|
| **Manufacturer:** | Abbott Vascular |
| **Addresses:** | 3200 Lakeside Drive<br>Santa Clara, CA 95054 USA |
| **Additional Manufacturing Sites:** | Abbott Vascular<br>26531 Ynez Road<br>Temecula, CA 92591 USA<br><br>Abbott Vascular<br>42301 Zevo Drive<br>Temecula, CA 92590 USA<br><br>Abbott Vascular<br>Cashel Road<br>Clonmel, County Tipperary, Ireland<br><br>Abbott Vascular<br>52 Calle 3, B31,<br>Coyol Free Zone,<br>El Coyol, Alajuela, Costa Rica |
| **Device Name:** | **XIENCE Xpedition SV, XIENCE Xpedition, XIENCE Xpedition LL, and XIENCE Xpedition 48 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 Xpedition and XIENCE Xpedition 48 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 |

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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

**Model Numbers:**

| Device Name | Stent Diameter (mm) | Stent Length (mm) | Model Number |
|---|---|---|---|
| **XIENCE Xpedition SV Everolimus Eluting Coronary Stent System** | 2.0 | 8 | 1070200-08 |
| | 2.0 | 12 | 1070200-12 |
| | 2.0 | 15 | 1070200-15 |
| | 2.0 | 18 | 1070200-18 |
| | 2.0 | 23 | 1070200-23 |
| | 2.0 | 28 | 1070200-28 |
| | 2.25 | 8 | 1070225-08 |
| | 2.25 | 12 | 1070225-12 |
| | 2.25 | 15 | 1070225-15 |
| | 2.25 | 18 | 1070225-18 |
| | 2.25 | 23 | 1070225-23 |
| | 2.25 | 28 | 1070225-28 |
| **XIENCE Xpedition Everolimus Eluting Coronary Stent System** | 2.5 | 8 | 1070250-08 |
| | 2.5 | 12 | 1070250-12 |
| | 2.5 | 15 | 1070250-15 |
| | 2.5 | 18 | 1070250-18 |
| | 2.5 | 23 | 1070250-23 |
| | 2.5 | 28 | 1070250-28 |
| | 2.75 | 8 | 1070275-08 |
| | 2.75 | 12 | 1070275-12 |
| | 2.75 | 15 | 1070275-15 |
| | 2.75 | 18 | 1070275-18 |
| | 2.75 | 23 | 1070275-23 |
| | 2.75 | 28 | 1070275-28 |
| | 3.0 | 8 | 1070300-08 |
| | 3.0 | 12 | 1070300-12 |
| | 3.0 | 15 | 1070300-15 |
| | 3.0 | 18 | 1070300-18 |
| | 3.0 | 23 | 1070300-23 |
| | 3.0 | 28 | 1070300-28 |
| | 3.25 | 8 | 1070325-08 |

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| Device Name | Stent Diameter (mm) | Stent Length (mm) | Model Number |
|---|---|---|---|
| | 3.25 | 12 | 1070325-12 |
| | 3.25 | 15 | 1070325-15 |
| | 3.25 | 18 | 1070325-18 |
| | 3.25 | 23 | 1070325-23 |
| | 3.25 | 28 | 1070325-28 |
| | 3.5 | 8 | 1070350-08 |
| | 3.5 | 12 | 1070350-12 |
| | 3.5 | 15 | 1070350-15 |
| | 3.5 | 18 | 1070350-18 |
| | 3.5 | 23 | 1070350-23 |
| | 3.5 | 28 | 1070350-28 |
| | 4.0 | 8 | 1070400-08 |
| | 4.0 | 12 | 1070400-12 |
| | 4.0 | 15 | 1070400-15 |
| | 4.0 | 18 | 1070400-18 |
| | 4.0 | 23 | 1070400-23 |
| | 4.0 | 28 | 1070400-28 |
| **XIENCE Xpedition LL Everolimus Eluting Coronary Stent System** | 2.5 | 33 | 1070250-33 |
| | 2.5 | 38 | 1070250-38 |
| | 2.75 | 33 | 1070275-33 |
| | 2.75 | 38 | 1070275-38 |
| | 3.0 | 33 | 1070300-33 |
| | 3.0 | 38 | 1070300-38 |
| | 3.25 | 33 | 1070325-33 |
| | 3.25 | 38 | 1070325-38 |
| | 3.5 | 33 | 1070350-33 |
| | 3.5 | 38 | 1070350-38 |
| | 4.0 | 33 | 1070400-33 |
| | 4.0 | 38 | 1070400-38 |
| **XIENCE Xpedition 48 Everolimus Eluting Coronary Stent System** | 2.5 | 48 | 1070250-48 |
| | 2.75 | 48 | 1070275-48 |
| | 3.0 | 48 | 1070300-48 |
| | 3.5 | 48 | 1070350-48 |

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 1989/686/EC on Personal Protective Equipment do not apply.

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This declaration is supported by an EC quality system (Annex II) and design examination certification listed below.

**Supporting Certificates:**
EC Quality Management System, ISO 13485:2003
Certificate Number: FM 72377
EC Design Examination Certificate Number: CE 632826
Annex II Certificate Number: CE 510108

**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 revision or with the obsolescence of the supporting Annex II and EC Design Examination certificates listed above.

This Declaration of Conformity is valid for the model numbers listed that were manufactured on or after April 13, 2015. The Declaration is also valid for rework activities executed after the date of effectivity for lots previously manufactured.

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

By: S Slane 9/15/15
Susan Slane,
Divisional VP, Global Quality and Compliance
Abbott Vascular

Place of issue: Temecula, CA Date of issue: 9/15/15

Effective Date: September 7, 2015