

DECLARATION OF CONFORMITY

Manufacturer: Abbott Vascular

Addresses: 3200 Lakeside Drive
Santa Clara, CA 95054 USA

**Additional
Manufacturing Sites:** 26531 Ynez Road
Temecula, CA 92591 USA

Cashel Road
Clonmel, County Tipperary, Ireland

Device Name: MULTI-LINK VISION® RX Coronary Stent System
MULTI-LINK VISION® OTW Coronary Stent System

Device Classification: Class III

Classification Rationale: The following Annex IX definition(s) apply to the “Product” for purposes of classifications: Per Rule 8, Annex IX, all implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended: to be used in direct contact with the heart, the central circulatory system, or the central nervous system, in which case they are in Class III.

**Authorized European
Representative:** Abbott Vascular International BVBA
Park Lane
Culliganlaan 2B
1831 Diegem, Belgium

MULTI-LINK VISION® RX Coronary Stent System

Product Description Stent Diameter(mm) /Stent Length(mm)	Model Number
2.75x08 mm RX	1007841-08
2.75x12 mm RX	1007841-12
2.75x15 mm RX	1007841-15
2.75x18 mm RX	1007841-18
2.75x23 mm RX	1007841-23
2.75x28 mm RX	1007841-28
3.0x08 mm RX	1007842-08
3.0x12 mm RX	1007842-12
3.0x15 mm RX	1007842-15
3.0x18 mm RX	1007842-18
3.0x23 mm RX	1007842-23
3.0x28 mm RX	1007842-28
3.5x08 mm RX	1007843-08
3.5x12 mm RX	1007843-12
3.5x15 mm RX	1007843-15
3.5x18 mm RX	1007843-18
3.5x23 mm RX	1007843-23
3.5x28 mm RX	1007843-28
4.0x08 mm RX	1007844-08
4.0x12 mm RX	1007844-12
4.0x15 mm RX	1007844-15
4.0x18 mm RX	1007844-18
4.0x23 mm RX	1007844-23
4.0x28 mm RX	1007844-28

MULTI-LINK VISION OTW Coronary Stent System

Product Description Stent Diameter(mm) /Stent Length(mm)	Model Number
2.75x08 mm OTW	1010137-08
2.75x12 mm OTW	1010137-12
2.75x15 mm OTW	1010137-15
2.75x18 mm OTW	1010137-18
2.75x23 mm OTW	1010137-23
2.75x28 mm OTW	1010137-28
3.0x08 mm OTW	1010138-08
3.0x12 mm OTW	1010138-12
3.0x15 mm OTW	1010138-15
3.0x18 mm OTW	1010138-18
3.0x23 mm OTW	1010138-23
3.0x28 mm OTW	1010138-28
3.5x08 mm OTW	1010139-08
3.5x12 mm OTW	1010139-12
3.5x15 mm OTW	1010139-15
3.5x18 mm OTW	1010139-18
3.5x23 mm OTW	1010139-23
3.5x28 mm OTW	1010139-28
4.0x08 mm OTW	1010140-08

Product Description Stent Diameter(mm) /Stent Length(mm)	Model Number
4.0x12 mm OTW	1010140-12
4.0x15 mm OTW	1010140-15
4.0x18 mm OTW	1010140-18
4.0x23 mm OTW	1010140-23
4.0x28 mm OTW	1010140-28

I, the undersigned, hereby declare that the medical devices specified above conform with the applicable *Essential Requirements* listed in Annex I and Annex II Part 4 of EC Council Directive 93/42/EEC.

This declaration is supported by an EC quality system and design examination approval (Annex II) under the supervision of the British Standards Institution, a notified body authorized by the United Kingdom Competent Authority. (EC Quality System Certificate Number: 510108, EC Certificate Number 71619)

By: SJ Slane Date: 5/24/10
Susan Slane
Divisional VP, Quality, Compliance, and Analytical Chemistry
Abbott Vascular